QUALITY CONTROL MANUAL

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MAINTENANCE OF ISOLATES FOR QUALITY CONTROL

STOCK CULTURES

Reference strains for quality control are originally obtained from ATCC, Microbiologicals or other commercial sources as lyophilised cultures. Follow manufacturer's instructions and subculture these lyophilised cultures. Upon receipt, each new strain will be will be entered in Soft like a patients specimen (see order entry instructions Appendix II - Ordering New QC Organisms in Soft) and then frozen in triplicate in the appropriate QC storage box. See Laboratory Information Systemsfor Freezing QC Strains in SoftStore.

Store the sub-cultured isolates in trisodium citrate glycerol at -70^{o}C. These frozen cultures are used as STOCK CULTURES and can be stored indefinitely at -70^{o}C. To replenish stocks, obtain from ATCC, Microbiologicals or other commercial sources as lyophilised cultures.

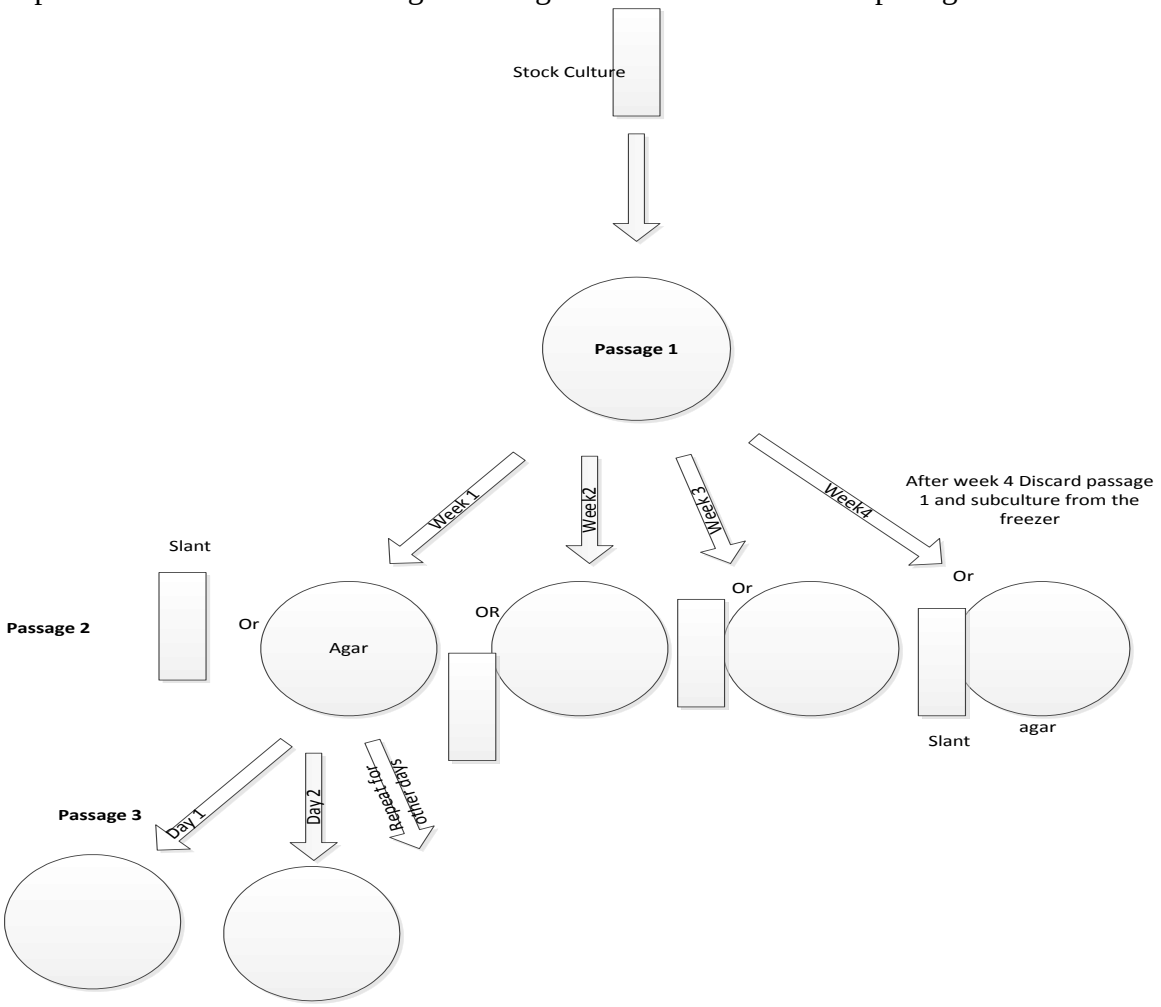
Stock cultures are subbed according to a schedule to maintain optimum performance. See Schedule for Subculture of Stock Cultures Table.

WORKING CULTURES

Working cultures are stored on TSB agar slants at 4^{o} to 8^{o}C or on Chocolate agar or Blood Agar for fastidious organism. See the Working List of Quality Control Organisms for storage requirements and freezer location.
These cultures are replaced monthly by sub-culturing twice to the appropriate solid media from the frozen Stock Cultures. The fresh subcultures are then placed in the appropriate racks and the previous months cultures are discarded.

Virus working cultures are propagated in the appropriate tube culture cell lines.

Example: Workflow for subculturing and using reference strains to show passages



CLSI- M07, 11th ed. Methods for dilution Antimicrobial Susceptibility tests for Bacteria that Grows Aerobically

- Store passage 1 subculture which is sub-cultured from the stock culture, in appropriate condition for the organism type for up to 4 weeks
- Subculture from passage 1 subculture onto agar slant or agar plate to prepare passage 2 subculture
- Subculture from passage 2 subculture onto agar plate to prepare passage 3 subculture
- Do not exceed more than 5 passages from the original master seed lot when sub-culturing viable microorganism

BEFORE TESTING

Before testing, cultures are sub-cultured from the working cultures onto solid media before use.

Not applicable for viruses

Note: The BioBalls are used for the Validation of Suitability for Rapid Product Sterility Testing by BacT/Alert Dual T System. Reference strains Preparation for each organism from the BioBalls are explained in Sterility Testing Manual Policy # MI_STER.

Schedule for Subculture of Stock Cultures							
Isolate #	Isolate	Sub monthly from freezer	Sub monthly to slants	Sub weekly from slants	Sub weekly from plates	Sub Mon/ Wed /Fri	Sub Mon/Fri
1	*Enterococcus gallinarum* 49573	**X**	**X**	**X**			
2	*Enterococcus faecalis* 49532	**X**	**X**	**X**			
3	*Enterococcus faecalis* 49533	**X**	**X**	**X**			
4	*Staphylococcus aureus* 8610	**X**	**X**	**X**			
5	*Staphylococcus aureus* 43300	**X**	**X**	**X**			
6	*Staphylococcus aureus* 43387	**X**	**X**	**X**			
7	*Klebsiella pneumoniae* 13883	**X**	**X**	**X**			
8	*Klebsiella pneumoniae* CAP 98	**X**	**X**	**X**			
9	*Proteus mirabilis* 12453	**X**	**X**	**X**			
10	*Proteus vulgaris* 13315	**X**	**X**	**X**			
11	*Escherichia coli* 0157 700728	**X**	**X**	**X**			
12	*Staphylococcus lugdenensis* 700328	**X**	**X**	**X**			
13	*Staphylococcus epidermidis* 12228	**X**	**X**	**X**			
14	*Staphylococcus aureus* 25923	**X**	**X**	**X**			
15	*Staphylococcus aureus* 29213	**X**	**X**	**X**			
16	*Staphylococcus saprophyticus*15305						
17	*Escherichia coli* 35218	**X**	**X**	**X**			
18	*Escherichia coli* 25922	**X**	**X**	**X**			
19	*Pseudomonas aeruginosa* 27853	**X**	**X**	**X**			
20	*Enterococcus faecalis* 29212	**X**	**X**	**X**			
21	*Enterococcus faecalis* 51299	**X**	**X**	**X**			
22	*Moraxella catarrhalis* 8176 CO_2	**X**			**X**		
23	*Streptococcus agalactiae* 12386 CO_2	**X**			**X**		
24	*Streptococcus* pyogenes 19615 CO_2	**X**			**X**		
25	*Streptococcus* sanguis 105556 CO_2	**X**			**X**		
26	*Streptococcus* Group F 12392 CO_2	**X**			**X**		
27	*Leuconostoc* species. CO_2	**X**			**X**		
28	*Haemophylus influenzae* 49427 CO_2 CHOC	**X**			**X**		
29	*Haemophylus parainfluenzae* 7901 CO2 CHOC	**X**			**X**		
30	*Haemophylus influenzae* B-lac+ 35056 CO_2 CHOC	**X**			**X**		
31	*Haemophylus influenzae* B-lac+ 35056 CO_2 CHOC	**X**			**X**		
32	*Streptococcus pneumoniae* 49619 CO_2	**X**			**X**		

Schedule for Subculture of Stock Cultures							
Isolate #	Isolate	Sub monthly from freezer	Sub monthly to slants	Sub weekly from slants	Sub weekly from plates	Sub Mon/ Wed /Fri	Sub Mon/Fri
33	*Streptococcus pneumonia* 6303 CO_2	**X**			**X**		
34	*Neisseria gonorrhoeae* 3069 CO_2 CHOC	**X**				**X**	
35	*Streptococcus equinus* C 9528 CO_2	**X**			**X**		
36	*Streptococcus equinus* G 12394 CO_2	**X**			**X**		
37	*Campylobacter jejuni* 29428 Microaerophilic	**X**				**X**	
38	*Shigella boydii* 9207	**X**	**X**				
39	*Shigella flexneri* 12022	**X**	**X**				
40	*Shigella sonnei* 25931	**X**	**X**				
41	*Shigella dysenteriae* 13313	**X**	**X**				
42	*Yersinia enterocolitica* 27729	**X**	**X**				
43	*Candida albicans* 10231	**X**	**X**	X			
44	*Candida tropicalis* 13803	**X**	**X**				
45	*Salmonella typhi* 19430	**X**	**X**				
46	*Bacteroides fragilis* 25285 ANO_2	**X**					**X**
47	*Salmonella paratyphi* 9150	**X**	**X**				
48	*Escherichia coli* 51446	**X**	**X**	**X**			
49	*Clostridium sordellii* 9714 ANO_2	**X**					**X**
50	*Staphylococcus aureus* 977	**X**	**X**	**X**			
51	*Staphylococcus aureus* 1026	**X**	**X**	**X**			
52	*Staphylococcus aureus* 976	**X**	**X**	**X**			
53	*Staphylococcus aureus* 700699	**X**	**X**	**X**			
54	*Staphylococcus aureus* 700698	**X**	**X**	**X**			
55	*Klebsiella pneumoniae* 1706	**X**	**X**	**X**			
56	*Klebsiella pneumoniae* 1705	**X**	**X**	**X**			
57	*Escherichia coli* N10-505	**X**	**X**	**X**			
58	*Escherichia coli* 8739	**X**	**X**	**X**			
59	*Enterococcus faecium* Vanc R	**X**	**X**	**X**			
60	*Klebsiella pneumoniae* String test +	**X**	**X**	**X**			
61	*Enterobacter aerogenes* ATCC 13048	**X**	**X**	**X**			
62	*Candida glabrata* ATCC MYA-2950	**X**	**X**	**X**			
63	*Escherichia coli* ATCC 35218	**X ***	**X**	**X ***			
64	*Klebsiella pneumoniae ATCC 700603*	**X ****	**X**	**X ****			

Schedule for Subculture of Stock Cultures							
Isolate #	Isolate	Sub monthly from freezer	Sub monthly to slants	Sub weekly from slants	Sub weekly from plates	Sub Mon/ Wed /Fri	Sub Mon/Fri
65	*Neisseria gonorrhoeae ATCC 49226*	**X**			**X**		
66	*Aspergillus brasiliensis ATCC 160404*	**X**	**X******	**X**			
67	*Haemophylus influenzae* B-lac- 10211 CO_2 CHOC	**X**			**X**		
68	*Neisseria gonorrhoeae ATCC 43069*	**Sub weekly from Freezer *****					
69	*Staphylococcus aureus 6538*	**X**	**X**	**X**			
70	*Bacillus subtilis 6633*	**X**	**X**	**X**			
71	*Pseudomonas aeruginosa 9027*	**X**	**X**	**X**			
72	*Clostridium sporogenes 19404 Ano2*	**X**					**X**

*Add ampicillin KB QC to E. coli 35218 upon stock removal from freezer AND upon each weekly sub.

**Add cefpodoxime KB QC to K. pneumoniae 700603 upon stock removal from freezer AND upon each weekly sub.

*** Sub Weekly from the freezer on Friday (or last weekday of the week) – ensure that we do not exceed more than 5 passages from the original master seed lot

**** Get the slant from the Mycology

CULTURE MEDIA QUALITY CONTROL

PROCEDURE FOR QC ON COMMERCIALLY PREPARED MEDIA:
All prepared media received will be examined visually for colour change, precipitate, lysis of blood, contamination etc. Any atypical observation should be brought to the attention of the QA technologist. An incident report formwill then be filled out and faxed to the supplier.

Performance quality control testing for routine commercially prepared media is not required except as per Media Requiring QC Table.
See media and reagent for quantity to select for QC bench for registration and QC when received.

Keep signed packing slip in the designated binder. Certificate of Analysis are online when needed. See manufacturer website for certificate.

MEDIA REQUIRING QC	
Aesculin Agar W/ Chloramphenicol, Gentamicin (EBM)	Macconkey Agar With Colistin CTCZ
All Homemade Media	Macconkey Agar Sorbitol
BHI Agar	Martin Lewis Agar
BHI Agar W/ ccg W/ 5% Sheep Blood	Mueller Hinton Agar
BHI Agar W/ Casein	Mueller Hinton Agar W/ 4% Salt
BHI W/ Gent 500, BHI W/ Strep 2000	Mueller Hinton Agar W/ 4% Salt, 6 mcg Oxacillin
BHI Agar W/ 6 mcg Vancomycin	Motility Tubes
Bile Esculin Plate	MR-VP
Campylobacter Agar	Reasoners 2A (R2A)
Candida Plus Agar	Visa Isolation Agar
Chromogenic Urine Biplate	
Chocolate Agar	**GMP media – Each new lot/shipment** Tryptic Soya Agar * Inhibitory Mold Agar * Fastidious Anaerobe Agar * Chocolate Agar * *Thioglycolate Broth* * *Tryptone Soya Broth* * *Tryptic Soya Agar Lec/Tween55* * *Tryptic Soya Agar Lec/Tween* *
Chromogenic Brilliance VRE Agar	
Chromogenic MRSA Denim Blue Agar	
Decarboxylase Base Broth	
Decarboxylase + Ornithine Broth	
Haemphilus Selective Agar	
Haemophilus Test Medium Agar	
Macconkey Agar With 2 µg /mL Cefpodoxime	

*** Quantitative GMP Media Quality Control - Prepare a working suspension for each microorganism:**

1. Subculture from the freezer vial into Chocolate for aerobes and into Brucella agar for anaerobes plate and incubate as per *Table 1*
2. For *Staphylococcus aureus, Pseudomonas aeruginosa, Neisseria gonorrhoeae, Haemophilus influenza, Bacteroides fragilis, Clostridium sordellii*[(2)] and *Candida albicans*[(1)]:
   - i. Prepare a standardized **0.5** McF of the 24 hours culture in Fluid A-ST (peptone water)
   - ii. Pipette 1mL of the 0.5 McF suspension into 9 mL Fluid A-ST **(A)**
   - iii. Pipette 1mL of (A) into 9 mL Fluid A-ST **(B)**
   - iv. Pipette 1mL of (B) into 9 mL Fluid A-ST **(C)**
   - v. Pipette 1mL of (C) into 9 mL Fluid A-ST **(D)**
   - vi. Pipette 1mL of (D) into 9 mL Fluid A-ST **(E)**
     NOTE [(1)]: for *C. albicans* - pipette 2ml of (D) to 6ml Fluid A-ST (E) then proceed to step 4.
   - vii. Pipette 1mL of (E) into 9 mL Fluid A-ST **(F)**
     NOTE [(2)]: for *C. sordellii* – pipette 5ml of (E) to 5ml Fluid A-ST (F)
   - viii. Proceed to step 4.
3. For *Aspergillus brasiliensis*[(3)] and *Bacillus subtilis*[(4)]:
   - i. Prepare a standardized **1.0** McF of the 24 hours culture in Fluid A-ST
     NOTE [(4)]: for *Bacillus subtilis* ensure suspension is mixed well
   - ii. Pipette 1mL of the 1.0 McF suspension into 9 mL Fluid A-ST **(A)**
   - iii. Pipette 1mL of (A) into 9 mL Fluid A-ST **(B)**
   - iv. Pipette 1mL of (B) into 9 mL Fluid A-ST **(C)**
   - v. Pipette 1mL of (C) into 9 mL Fluid A-ST **(D)**
     NOTE [(3)]: for *A. brasiliensis* proceed to step 4
   - vi. Pipette 1mL of (D) into 9 mL Fluid A-ST **(E)**
   - vii. Pipette 1mL of (E) into 9 mL Fluid A-ST **(F)**
   - viii. Proceed to step 4.
4. Dispense 0.2ml of final dilution to in-use lot of GMP media that requires quantitative QC and perform colony count to determine **CFU/ml of working solution.**
5. Dispense 0.2ml of final dilution to NEW lot to compare against old lot.
6. Document the result in the Quantitative GMP Media Quality Control chart in TotalQC (TQC) and the QA tech will review upon completion

PROCEDURE FOR QC ON COMMERCIALLY PREPARED MEDIA (cont'd):

1. To create Parameter Control Labels for any of the above media, see hyperlink referring to Printing QC Control Labels, OR go to "Print Labels" on the toolbar, and it will bridge over to SoftTotalQC (TQC). Media that is needing QC will appear in the "Receiving Worklist"

under "QC Media on Receipt". Select "Parameter Control Labels" on the bottom. Uncheck any items you do not want labels for, then click "Network Printer" and find your printer from the list. Once a printer has been selected click "Run". If multiple copies of labels are needed, you can edit the label number using the arrows in the copies section or manually enter a number.
(Note: If you have more than 1 lot number for a particular media type, you can search for the lot number using the search bar, or exit the receiving list after ordering the labels for the first lot and choose the next order in the worklist for each subsequent lot.)

2. Each item/media should already be registered into the "TotalQC" module of SOFT. See Appendix VI - SOFT for TotalQC.

3. For **Oxacillin, NACL, VISA, BHI with casein, VANCO, and High level Gent/Strep plates:**
   i. QC must also be done each day the plate is used. Test QC organisms on each plate as they are set up with clinical isolates. The LIS "VITEK QC" worklist will generate testing requirements as scheduled.
   ii. **Print a barcoded lot label for each plate received by doing the following:**
   - In TQC under "Tools" choose "Print Labels"
   - Enter the Lot# in the Search Window and click "Search"
   - Choose "Lot Label"
   - Edit the number of labels in the copies section by using the arrows or type in the desired number
   - Click "Network Printer" and search for the printer from the drop down list
   - Click "Run"
   - **Elastic the plates with their respective labels and place in the accordingly labeled plastic bins in the refrigerator by QC bench (MIRM22). Be sure to put newest lots to the back of the shelf and move older lots forward.**

4. Using the testing labels generated, label a saline tube for suspensions of each organism required, and affix one label to the media being tested and another label for 1 representative purity plate for each organism.

5. For all isolates except *N. gonorrhoeae, H. influenzae and C. jejuni*:
Prepare a saline suspension of all required isolates to a turbidity to match 0.5 McFarland Standard. Inoculate media using a calibrated 1µL (0.001 mL) loop. Incubate as required and inspect cultures at 24 and 48 hours.

6. For *N. gonorrhoeae, H. influenzae and C. jejuni*:

Prepare a saline suspension of all required isolates to a turbidity to match 0.5 McFarland Standard. Make a 1:10 dilution; remove 300ul from a standard blank Vitek saline tube (3.0mL) and pipette 300uL of the 0.5 McFarland suspension into the saline.

7. Inoculate media using a calibrated 1µL (0.001 mL) loop. For Oxacillin Screen, QUAD and Vancomycin Screen plates inoculate with a swab.

8. Incubate as required and inspect cultures at 24 and 48 hours.

9. Use the keypads to record the results in TQC. The result will change to a green colour if an acceptable result is obtained. Once QC has passed put the product into circulation. See Organisms for Media QC and Expected Results table below for expected results.

10. If expected results are not attained, follow Out of Range Results Section

ORGANISMS FOR MEDIA QC AND EXPECTED RESULTS		
MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
AESCULIN AGAR W/ CLORAMPHENICOL, GENTAMICIN (EBM)	*C. neoformans* ATCC 76484	Brown
	C. glabrata ATCC 2001	Clear
	E. coli ATCC 25922	No growth
BHI AGAR	*E. faecalis* ATCC 49532	Growth
	E. faecalis ATCC 49533	Growth
	E. gallinarum ATCC 49573	Growth
BHI AGAR W/ CCG/5% SHEEP BLOOD	*T. mentagrophytes* patient strain 9533	Growth
	C. albicans ATCC 10231	Growth
	E. coli ATCC 25922	No growth
BHI AGAR W/ CASEIN	*S. aureus* ATCC 8610	Growth
	S. aureus ATCC 43300	Growth
	S. aureus ATCC 29213	Growth
	S. aureus ATCC 43387	Growth
BHI AGAR W/ GENT 500, BHI W/ STREP 2000	*E. faecalis* ATCC 49532	Gent-Growth Strep-No growth
	E. faecalis ATCC 49533	Gent-No growth Strep-Growth
	E. gallinarum ATCC 49573	Gent-No growth Strep-No Growth
BHI AGAR W/ 6 MCG VANCO	*E. faecalis* ATCC 49532	No growth
	E. faecalis ATCC 49533	No growth
	E. gallinarum ATCC 49573	Growth
BILE ESCULIN PLATE	Growth	Growth
	S. pyogenes ATCC19615	No growth

ORGANISMS FOR MEDIA QC AND EXPECTED RESULTS		
MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
* Use the 1:10 dilution of the 0.5 McFarland suspensions for inoculation.		
CAMPYLOBACTER AGAR	*Campylobacter jejuni* ATCC 29428*	Growth
	E. coli ATCC 25922	No growth
CANDIDA PLUS AGAR	*C. auris MYC-5001*	Light blue with blue halo, blue on the back side
	C. albicans 10231	Green-blue
CARROT BROTH	*S. agalactiae ATCC 12386*	Orange + growth
	S. pyogenes ATCC 19615	No colour + Growth
	E. coli ATCC 25922	No colour + No growth
CHROMOGENIC BRILLIANCE AGAR (VRE)	*E. faecalis* ATCC 51299	Blue colonies
	E. gallinarum ATCC 49573	No growth
	E. faecalis ATCC 29212	No growth
	E. coli ATCC 25922	No growth
	C. albicans ATCC 10231	No growth
	E. faecium	Purple colonies
CHROMOGENIC DENIM BLUE AGAR	*S. epidermidis* ATCC 12228	No growth
	S. aureus ATCC 43300	Blue colonies
	S. aureus ATCC 29213	No growth
	S. aureus LPTP 8610	Blue colonies
	E coli ATCC 25922	No growth
	E. faecalis ATCC 29212	No growth
CHROMOGENIC URINE BIPLATE	*E.coli* ATCC 25922	Burgandy pink
	E. faecalis ATCC 29212	Blue
	P. vulgaris ATCC 13315	Brown
	S. aureus ATCC 25923	White
DECARBOXYLASE BASE	S. *lugdunensis* ATCC 170032	Yellow

ORGANISMS FOR MEDIA QC AND EXPECTED RESULTS		
MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
BROTH	*S. aureus* ATCC 25923	Yellow

* Use the 1:10 dilution of the 0.5 McFarland suspensions for inoculation.

DECARBOXYLASE + ORNITHINE BROTH	*S. lugdunensis* ATCC 170032	Purple
	S. aureus ATCC 25923	Yellow
HAEMOPHILUS SELECTIVE AGAR	*S. aureus* ATCC 29213	No growth
	H. influenzae ATCC 10211*	Growth
HAEMOPHILUS TEST MEDIUM AGAR	*H.influenzae* ATCC 494227	Ampicillin 13-21mm Ceftriaxone 31-39mm
	H. influenzae ATCC 10211	Growth
MACCONKEY AGAR W/ 2 µG/ML CEFPODOXIME	*K. pneumonia* Cap 98D	Growth
	K. pneumonia ATCC 13883	No growth
MACCONKEY AGAR W/ COLISTIN CTCZ	S. marcescens ATCC 12820	Growth
	E. coli ATCC 25922	No growth
MACCONKEY AGAR SORBITOL	*E. coli* ATCC 25922	Pink
	E. coli LPTP 0157:H7 8608-3	Colourless
MARTIN-LEWIS AGAR	*N. gonorrhoeae* ATCC 43069*	Growth
	P. mirabilis ATCC 12453	No growth
	S. epidermidis ATCC 12228	No growth
MUELLER HINTON AGAR WITH GENTAMICIN 10µg DISC	*P. aeruginosa* ATCC 27853	16-21 mm zone
MUELLER HINTON AGAR WITH TMP/SMX DISC	*E. faecalis* ATCC 29212	≥20 mm zone
MUELLER HINTON AGAR	*S. aureus* ATCC 8610	Growth

ORGANISMS FOR MEDIA QC AND EXPECTED RESULTS		
MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
W/4% SALT 6 mcg OXACILLIN	*S. aureus* ATCC 43300	Growth
	S. aureus ATCC 29213	No growth
	S. aureus ATCC 43387	No growth / Haze

* Use the 1:10 dilution of the 0.5 McFarland suspensions for inoculation.

MUELLER HINTON AGAR W/ 4% SALT	*S. aureus* ATCC 8610	Growth
	S. aureus ATCC 43300	Growth
	S. aureus ATCC 29213	Growth
	S. aureus ATCC 43387	Growth
MOTILITY TUBES	*E. coli* ATCC 25922	Positive
	K. pneumo ATCC 13883	Negative
MR-VP	*S. pyogenes* ATCC19615	Negative
	S. Gp. F ATCC 12392	Positive
PYRUVATE AGAR	*N. brasiliensis* (patient) 19296	Growth
	E. coli ATCC 25922	No Growth
Reasoners 2A (R2A) Agar	*S. aureus* ATCC 25923	Growth
	E.coli ATCC 25922	Growth
VISA ISOLATION AGAR	*S. aureus ATCC 700698*	Growth
	S. aureus ATCC 700699	Growth
	E. gallinarum ATCC 49573	Growth
	S. aureus ATCC 43300	No growth
	S. aureus ATCC 29213	No growth
	S. aureus LPTP 8610	No growth
GMP Media - QC required –Each new lot or shipment :		

ORGANISMS FOR MEDIA QC AND EXPECTED RESULTS		
MEDIA	**ORGANISMS**	**EXPECTED RESULTS**
THIOGLYCOLATE BROTH	*S. aureus* ATCC *6538* *P. aeruginosa* ATCC *9027* *C. sporogenes* ATCC *19404* Uninoculated	Growth Growth Growth No growth
TRYPTICASE SOYA BROTH	*B. subtilis* ATCC *6633* *C. albicans* ATCC *10231* *A. brasiliensis* ATCC *16404* Uninoculated	Growth Growth Growth No growth
Tryptic Soya Agar Lec/Tween 55 Tryptic Soya Agar Lec/Tween Tryptic Soya Agar	*B. subtilis* ATCC *6633* *C. albicans* ATCC *10231* *A. brasiliensis* ATCC *16404* *S. aureus* ATCC 6538 P. aeruginosa ATCC 9027 Uninoculated	** ** ** ** ** No Growth
Fastidious Anaerobic Agar (Brucella Agar)	*B.fragilis* *C.Sordelli* Uninoculated	** ** No Growth
Inhibitory Mold Agar	*C. albicans* ATCC *10231* *A. brasiliensis* ATCC *16404* Uninoculated	** ** No Growth
CHOCOLATE AGAR	*N. gonorrhoeae* ATCC 43069* H. Influenzae ATCC 10211 Uninoculated	** ** No Growth

**** Compare amount of growth on new lot compared to old lot using the same working suspension. Refer to Prepare a working suspension**

PROCEDURE FOR QC ON MEDIA PREPARED IN-HOUSE:

Visual inspection includes observing the media for colour change, precipitate, lysis of blood, etc. Any atypical observation should be brought to the attention of the QA technologist. If the medium is visually satisfactory, write "OK" in the space provided.

pH testing will be performed on the final medium after it has solidified and cooled to room temperature. Record the value obtained in micqc Results Entry List "Procedure Actions" Comment (F7).

For blood that has been added to freshly prepared agar, one drop is put onto BA and incubated at 35^{o}C for 48 hours and then at RT for a further 48 hours.

Sterility testing will be performed on all media prepared in our laboratory. One plate or tube from each batch will be incubated at 35^{o}C for 48 hours, one at room temperature for 48 hours. Performance testing will be done using the Standard Loop method. One plate from each batch will be tested when first prepared and again on each successive 7 days until the supply in the refrigerator is depleted or the expiry date is reached.

If expected results are not attained, follow Out of Range Results Section

Results will be documented in LIS.

ANTIBIOTIC QUALITY CONTROL

Antibiotics are tested weekly on the QC bench. LIS VITEK QC worklist will generate testing requirement on scheduled day. See FREQUENCY OF TESTING for further QC frequency.

For a Complete list of antibiotic inventory see: Purchasing and Inventoryforms

Rarely used antibiotics must be run with controls per use and documented on the Rarely Used Antimicrobial Recording Chart in Appendix VIII.

PROCEDURE:

A. LOT REGISTRATION

All new lots of antibiotics and e-tests must be registered into the QC program. All antibiotics and Etests will be given to the QC bench on receipt after entry into TQC. For shipments requiring registration follow Appendix VII: Registering Antibiotics.

B. CONTROL STRAIN PREPARATION

1. To control the precision and accuracy of the test procedure, the following organisms are to be maintained:

Staphylococcus aureus	ATCC 25923
Staphylococcus aureus	ATCC 29213
Staphylococcus aureus	ATCC 700698
Staphylococcus aureus	ATCC 700699
Staphylococcus epidermidis	ATCC 12228
Staphylococcus saprophyticus	ATCC 15305
Enterococcus faecalis	ATCC 29212
Streptococcus pneumoniae	ATCC 49619
Escherichia coli	N10-505
Escherichia coli	ATCC 35218
Pseudomonas aeruginosa	ATCC 27853
Klebsiella pneumoniae	ATCC 1705
Klebsiella pneumoniae	ATCC 1706
Klebsiella pneumoniae	ATCC 700603
Haemophilus influenzae	ATCC 49247
Haemophilus influenzae	ATCC 10211
Neisseria gonorrhoeae	ATCC 49226

2. Before testing, cultures are subcultured from the TSB working culture slants to Blood agar. Note: (*Haemophilus* is subcultured once per week from Chocolate agar and stored at 4C).

3. Continue to use these cultures as long as there is no significant change in the mean value diameter that cannot be attributed to methodology. Obtain fresh cultures from the ATCC or any reliable commercial source.

4. Follow procedure described in the Antibiotic Susceptibility section of the lab manual.

C. ANTIBIOTICS TO BE TESTED

Test the control organisms using the antimicrobial discs/Etests which are used to test clinical isolates. The discs/Etests currently in use and the appropriate organisms for testing are listed in tables for: Kirby Bauer Disk QC, ROSCO Disks QC and Etest QC.

1. See in susceptibility manual for antibiotic codes. The stock supply of discs is found in freezer MIFA. The working racks of discs/Etests are placed in the walk-in fridge each night. When replacing a vial from the stock supply, write the date in use and your initials on the vial.
   Note: There is also a rack labelled "Rarely Used Antibiotics" in MIFA.

2. The disks/Etests on the working discs rack are tested for Quality Control weekly and the "Rarely Used Antibiotics" are tested for Quality Control whenever a patient test is done.

3. Each new batch of Mueller Hinton agar must be tested for unsatisfactory levels of inhibitors. This is done by performing the tests with *E. faecalis* (ATCC 29212) and sulfonamide and trimethoprim/sulfamethoxazole (co-trimoxazole) discs.

D. ZONE SIZE / MIC LIMITS

Enter zone diameters into the corresponding TQC order. Maximum and minimum zone diameters/MIC that should be observed with a single control test can be found in the expected ranges column of the QC order as well as in CLSI M100.

(a) No more than one out-of-control result in 20 consecutive control tests is allowed. Any more than this requires corrective action.
(b) Anytime corrective action is taken the count of 20 begins again.

E. FREQUENCY OF TESTING

1. Each new lot of Mueller Hinton agar must be tested and documented.

2. Each new type of antimicrobial discs/Etests must be tested with appropriate control strains **before** being introduced into routine use. Preferably this will be done when the discs arrive in the laboratory.

3. The overall performance of the procedure should be monitored daily. Weekly monitoring will be done in this laboratory provided that the following conditions exist:

   (a) Documentation that the control strains were tested for 30 consecutive test days
   (b) No more than 3 of the 30 zone diameters were outside the accuracy control limits stated in Table 2.

4. When these requirements are fulfilled, each control strain must be tested:
   (i) Once a week
   (ii) Whenever any reagent component is changed

5. M2/M7 CLSI If any zone diameter is outside the control limit when tested weekly, you must return to daily testing until the problem is resolved. If resolution of the problem cannot be resolved, you must continue daily control tests. To return to weekly testing, documentation of satisfactory performance for another 30 consecutive days must be done.

F. RESOLUTION OF THE PROBLEM

1. Resolution of any problem must be documented in TQC as a "Result Action" 

2. Use "M_REPEAT" and enter any resolutions in the comments section.

3. Inform QA or charge technologist of all out-of-range results.

4. See CLSI M100 Table 3D- Disc Diffusion QC Troubleshooting Guide for corrective action suggestions.

5. Corrective Action during Daily Testing.

   (a) One out-of-control measurement is not cause for immediate attention.

(b) Corrective action must be taken if any of the following circumstances arise:

(i) 2 consecutive measurements of any drug-microorganism combination fall outside the range
(ii) 3 or more in 20 consecutive test results fall outside the range

6. Corrective Action during Weekly Testing.

If a value falls outside the accuracy control/limits, the following are required:

(a) Appropriate control strain(s) must be tested for 5 consecutive test days.

(b) For each drug-microorganism combination, all 5 zones must be within the accuracy control limits.

(c) If any result is outside the accuracy or precision control limits, daily control testing must be resumed for a minimum of 30 consecutive test days.

	ANTIBIOTICS TO BE TESTED FOR KIRBY BAUER QC – 0.5 McFarland						
KB Disk Abbrev	***S. aureus*** **ATCC 25923**	***E.coli*** **ATCC 25922**	***E.coli ATCC 35218***	***K. pneumoniae ATCC 700603***	***P.aeruginosa*** **ATCC 27853**	***H.influenzae*** **ATCC 49427**	***S.pneumoniae*** **ATCC 49619**
	3 small MH	**2 large MH**	**1 small MH**	**1 small MH**	**2 small MH**	**1 HTM**	**1 MH Blood**
	BA PP	**MAC PP**			**MAC PP**	**CHOC PP**	**BA PP**
LEV							X
E	X						X
OX	X						X
DA	X						X
VA	X						X
CN	X	X			X		
KZ	X	X					
P	X						
SXT	X	X					
TE	X	X					
DX	X	X					
RD	X						
MUP	X						
AM		X	**X**			X	
CRO/CAX		X				X	
F		X					
TOB		X			X		
CAZ		X		X	X		
CP		X					
MEM		X					
AMC			**X**				
ATM		X					
CPD		X					
FOX		X					
FEP		X					
ETP		X					
AMK					X		
TZP			X				
CPD				X			
TIM			X				
DO	X	X					

KB Disk Abbreviation	***H.influenzae* ATCC 49427**
	CHOC PP
Growth	X

ROSCO DISKS TO BE TESTED FOR QC AND EXPECTED RESULTS			
KB Disk Abbreviation	***K. pneumoniae* ATCC 1705**	***K. pneumoniae* ATCC 17056**	***E coli* N10-505**
	1 large MH	**1 large MH**	**1 large MH**
	Set up plates using 0.5 McFarland Suspensions with MAC PP		
Meropenem 10	15 – 20 mm	28 – 35 mm	11 – 16 mm
Mero10+DP	15 – 20 mm	28 – 35 mm	25 – 30 mm
Mero10+BO	22 – 28 mm	28 – 35 mm	11 – 16 mm
Mero10+CL	15 – 22 mm	28 – 33 mm	11 – 16 mm
Temocillin	12 – 35 mm	12 – 35 mm	9 – 11 mm
Differential Characteristic	DP<5, **BO≥5**, CL <5 mm TEMO=S	DP<5, BO<5, CL<5 mm TEMO=S	**DP ≥5**, BO<5, CL <5 mm TEMO=R

	ANTIBIOTICS TO BE TESTED FOR Etest QC – 0.5 McFarland					
Etest Disk Abbreviation	*S. aureus* ATCC 29213	*E. coli* ATCC 25922	*P. aeruginosa* ATCC 27853	*E. faecalis* ATCC 29212	*K. pneumoniae* ATCC 700603	*S. pnemoniae* ATCC 49619
	6 small MH	2 small MH	3 small MH	1 small MH		2 MH Blood
	BA PP	MAC PP	MAC PP	BA PP		BA PP
VA	X					X
P	X					X
MUP	X					
FU	X					
TP	X					
LZ	X					
QDA	X					
LE	X					
CT	X					
C/T			**X**		**X**	
TX	X					X
TGC		X		X		
TS		X				
TZ	X					

ANTIBIOTICS TO BE TESTED FOR Etest QC – 2.0 McFarland			
Etest Disk Abbreviation	***S. aureus* ATCC 29213**	***S. aureus* ATCC 698**	***S. aureus* ATCC 699**
	1 BHI Casein	**1 BHI Casein**	**1 BHI Casein**
	BA PP	**BA PP**	**BA PP**
VA	X	X	X
TP	X	X	X

REAGENT AND TEST KITS QUALITY CONTROL

REGISTERATION OF REAGENT AND TEST KITS:

Date all reagents and test kits on receipt. Register them into TQC and set them to "Active" even if the reagent or test kit is not being used immediately.

When reagents and/or test kits are being placed into use, write “In-Use” on the item along with the “Date” of in use ".

FREQUENCY OF TESTING:

All required QC for reagents and test kits will appear in the QC worklists in TQC.

On Receipt QC:

Acridine orange	Kovacs
ALA discs	LAP discs
Aminopeptidase (Bactident)	
API 20E strips	Optochin
API 20NE strips	Oxidase droppers
API NH strips	PBP2A Kit
βCARBA	Phadobact Kit
βLACTA	PYR Kits
Bacitracin discs	Rosco
Catalase (hydrogen peroxide)	Saline (3ml & 0.5mL)
Cefinase discs	Salmonella serology
Cryptococcal Antigen Latex kits	Shigella serology
Desoxycholate (Bile solubility) droppers	Staph-Plus Pastorex kits
E. coli O157 Test kits	Strep group Prolex Reagents 1,2,3, ABCDFG
Eosinophil Stain	Tributyrin discs
FAB broth	Tube coagulase
Ferric Chloride	TREK panels
Fungi flour stain	VITEK cards
Horse serum	Welcollex
Indole spot reagent	ZN Stain kits: Kinyouns, Modified Kinyouns and Auramine Rhodamine
James	

PROCEDURE:

Perform QC on test kits and reagents as described in the technical manuals. For kits which require freshly subcultured control organisms for QC (namely API, Rapid ANA, and Vitek cards), print labels as per Appendix IV: Printing QC Control Labels.

Labels can be used for subculture of organisms from freezer stocks, the test itself, API/ Rapid ANA code sheets, and purity plates as required.

For kits that have their own internal controls, follow procedure described in the Technical section of the lab manual. Enter the results into TQC.

If expected results are not attained, follow Out of Range Results Section

Saline sterility testing:
For 3ml & 0.5mL saline tubes only.
Each batch of saline received must be tested for sterility. Two saline tubes from each box must be tested.

- Mark the saline tubes accordingly to trace them back to their respective boxes
- Label one BA plate for each saline tube
- Remove 1mL from each saline to inoculate onto the BA
- Incubate as below for a total of 48hours
- Report growth or no growth for the entire shipment received

Media	**Incubation**	
Blood Agar (BA)	CO_2,	35^oC x 24 hours
	O_2	RT^oC x 24 hours

F.A.B sterility testing:
Each batch of Fastidious Anaerobic Broth received must be tested for sterility.
Two FAB tubes must be tested from each box received.

- Mark the FAB tubes accordingly to trace them back to their respective boxes.
- Incubate as below for a total of 4 days.
- Report growth or no growth for the entire shipment received.

Media	**Incubation**	
Fastidious Anaerobic Broth (THIO)	CO_2,	35^oC x 48 hours
	O_2	RT^oC x 48 hours

EQUIPMENT MAINTENANCE & QUALITY CONTROL

For Equipment Maintenance refer to Equipment Maintenance Procedure QEQMI03001

Anaerobic Jars

Match the label of the jar and the lid.
Include the following in each anaerobic jar set up:

QC Item	Expected Result:
Anaerobic Indicator strip (OXOID)	Colourless within 2 hours of set up and remains colourless until the jar is opened
*P. aeruginosa**	No growth
*B. fragilis**	Growth
*C. sordellli**	Growth

Enter results into TQC under the respective bench QC worklists (ie: Blood Bench for AnO2 Jars).
* Not required for 24 hours throat culture jars.

If expected results are not attained, follow Out of Range Results Section

Campylobacter Jars

Match the label of the jar and the lid.
Include the following in each anaerobic jar set up:

QC Item	Expected Result:
C. jejuni	Growth

Enter results into TQC under the respective bench QC worklists.

Lab Equipment/Analyzers

Records of all preventive maintenance and repair work performed by Field Service Engineers (FSE) into TQC under the Equipment Maintenance Record for that piece of Equipment/Instrument.

Perform QC after each preventive maintenance done on the Instrument/Analyzer
If expected results are not attained, follow Out of Range Results Section.

SEROLOGY / VIROLOGY QC

All new reagents lots will be tested using either prepared external controls and/or commercially available reference material (where available) before being placed into service. Reagents must be opened in TQC prior to use and their statuses changed to "Active".

All Serology tests require QC run in parallel with each clinical sample test run. Refer to the appropriate tests for procedures and methods.
See Serology Manual and.

Record all QC results into TQC.

If expected results are not attained, follow Out of Range Results Section.

QUALITY CONTROL REVIEW

Inform all out-of-range results to the Charge Technologist, Senior Technologist or Quality Assurance Technologist.

Charge technologists are responsible for reviewing overdue Quality Control procedures **weekly** with responsible bench technologists.
Obtain lists of overdue QC procedures from the TQC program:

From TQC main menu

1. Open the Results tab → Click on Resulting Worklists
2. Enter "M_" in the Worklist ID and click "Search for Worklist"
3. Select "M_PENDING_BACTIQC" for Bacteriology Pending and "M_PENDING_VIROQC" for Virology Pending
4. Double click on the worklist or click Run Worklist
5. To print worklist, select "Worklist Report"
6. Choose Network Printer and select the printer from the drop-down list
7. Click "Run"

Charge technologist, Senior Technologist or Quality Assurance Technologist will verify all Quality Control results **weekly**. All procedures will be verified in TQC.

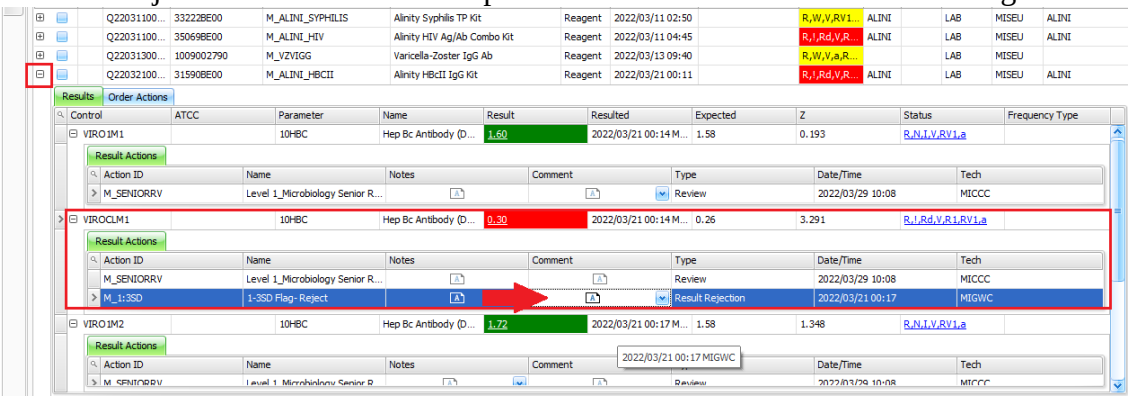
- Obtain lists for verification from the TQC program:
  - From the TQC main menu:

1. Open the Review Tab → Click on "Review Worklist"
2. Enter "M_" in the Worklist ID and click "Search for Worklist"
3. Select from the list "M_REVIEW_MONTHLY"
4. Double click on the worklist or click Run Worklist
5. Items that are within range will display in Green, Result Warnings will display in Yellow, and Results Out-of-Range will display in Red.
6. To review an item, click the check box beside the desired items
7. Select "Quick Review Orders"
8. Choose the Level (Level 1 – senior, Level 2 – charge) from the top of the review box
9. Select an Action ID from the drop-down list; either M_SENIORRV or M_CHARGERV
10. If needed, comments can be entered into the comment field
11. Click "OK"
12. In the "Status" column you should now see an RV1 or RV2 beside the other letters showing that this order has now been reviewed
13. Once finished reviewing all results, click "Refresh"
14. All the reviewed orders should disappear from the worklist

For Serology/Virology tests, QC verifications by seniors are only done for Out-of-Range results in TQC.

- Obtain lists for verification from the TQC program:
  - From the TQC main menu:

1. Open the Review Tab → Click on Review Worklist
2. Enter "M_" in the Worklist ID and click "Search for Worklist"
3. Select from the list "M_REVIEW_VIROLOGY"
4. Double click on the worklist or click Run Worklist
5. Result Warnings will display in Yellow, and Results Out-of-Range will display in Red. **Note: Items that are within range will not display in this worklist.**
6. If you wish to review the Result Rejection comments, expand the + sign and the result rejection comments will be present under the result that is out of range

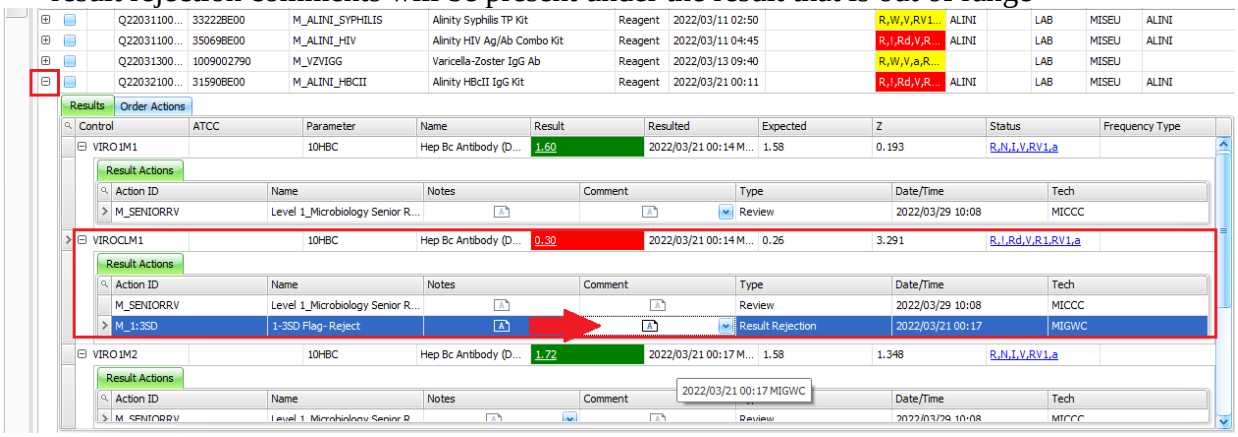


7. Click on the drop-down arrow to review the comments
8. To review the results, click the check box beside the desired item(s)
9. Select "Quick Review Orders"
10. Choose the Level (Level 1 – senior, Level 2 – charge) from the top of the review box
11. Select an Action ID from the drop-down list; either M_SENIORRV or M_CHARGERV
12. If needed, comments can be entered into the comment field
13. Click "OK"
14. In the "Status" column you should now see an RV1 or RV2 beside the other letters showing that this order has now been reviewed
15. Once finished reviewing all results, click "Refresh"
16. All the reviewed orders should disappear from the worklist

The Laboratory Supervisor will perform **Monthly** review of all Quality Control procedures.

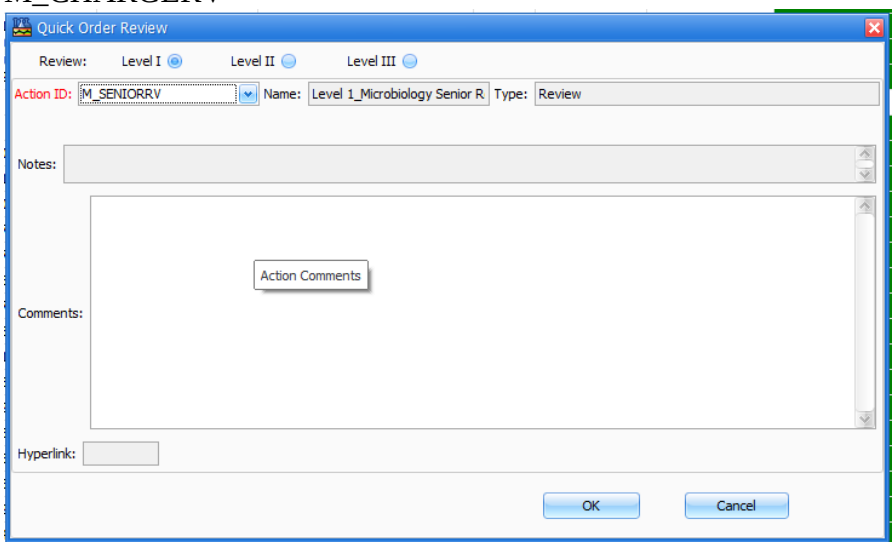
- From TQC main menu:

1. Open the Review Tab → Click on Review Worklist
2. Enter "M_" in the Worklist ID and click "Search for Worklist"
3. Select from the list "M_REVIEW_MONTHLYQC"
4. Double click on the worklist or click Run Worklist
5. Items that are within range will display in Green, Result Warnings will display in Yellow, and Results Out-of-Range will display in Red.
6. If you wish to review the Result Rejection comments, expand the + sign and the result rejection comments will be present under the result that is out of range



7. Click on the drop-down arrow to review the comments
8. To review the results, click the check box beside the desired item(s)
9. Select "Quick Review Orders"
10. Choose the Level (Level 1 – senior, Level 2 – charge) from the top of the review box

11. Select an Action ID from the drop-down list; either M_SENIORRV or M_CHARGERV



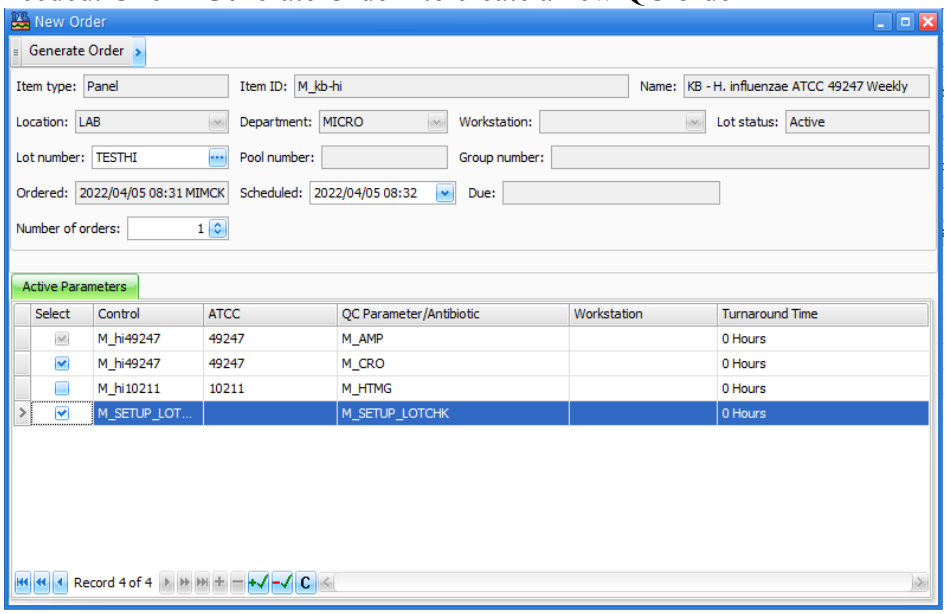
12. If needed, comments can be entered into the comment field
13. Click “OK”
14. In the “Status” column you should now see an RV1 or RV2 beside the other letters showing that this order has now been reviewed
15. Once finished reviewing all results, click “Refresh”
16. All the reviewed orders should disappear from the worklist

	Planting	Gram Stain	Blood Culture Accessioning	Blood Culture 1 & 2	Respiratory	Urine	WASP Lab
Daily	Clean Centrifuge Biosafety Cabinet Cleaning / Pressure / Settle Plates - Resp - Gynae / Misc - IC - VRE - Urine Isoplater GeneXpert Gram Stain Instrument	Gram stain Kohler Mic1 Kohler Mic2 Kohler Mic3	Biosafety Cabinet Cleaning /Pressure/ Settle Plates Bench QC duties Vitruo Worklists Gram stain Bench Top Kohler	Vitek MS Catalase x2 Oxidase x2 Staph agglu. X2 PYR Densichek x2 Bench Top x2 Heating Block x2 Anaerobic Jar x2	Catalase Oxidase Staph agglu. Cefinase Cetrimide Heating Block Densichek Bench Top x2 Anaerobic Jar x2	Catalase Oxidase Staph agglutination Densichek x2 Bench Top x2 **From Planting QC:** Isoplater Reader WASP settle plates WASP sterility plates	Catalase Oxidase Staph agglutination Densichek x2 Bench Top x2 Vitek MS
Weekly	GeneXpert Isoplator Maintenannce		Weekly Checklist	Weekly Checklist - BC1 Weekly Checklist - BC2	Weekly Checklist Weekend Reminders	Weekly Checklist UR1 Weekly Checklist UR2	
Monthly	GeneXpert						
Bi-Annual			Freezer MIFF Cleaning				
When used		Eosinophil stain ZN Modified ZN Acridine Orange FA Stain (AFB)	Acridine Orange Aminopeptidase	Ornithine Germ Tube LAP Acridine Orange String Test Bacitracin	Germ Tube ALA Acridine Orange	Spot Indole LAP	
On Receipt							

	Wounds	Genitals / Enterics	Infection Control	Mycology	QC	Vitek
Daily	Catalase x 3 Oxidase x 3 Staph agglu.x 3 Anaerobic Jar x3 Heating Block Densichek x3 Bench top x3 Check Vitek Clean Vitek	Catalase Oxidase Staph agglutination Densichek Bench Top Campy Jar QC	Catalase Oxidase Staph agglutination Vitek MS Densichek GeneXpert Water bath Bench top	Biosafety Cabinet : Cleaning /Pressure/ Settle Plates Lacto Phenol Aniline Blue Fungi-Fluor Stain Kohler Bench Top	Densichek Sterility Heating Block x2 Attest incubator x2 Bench Top x2	Read temp Read Optics Empty Waste Room temp / humidity Densichek *S. aureus* 8610 sub QUAD / Ox / Vanc
Weekly	Weekly Checklist M1 Weekly Checklist M2 Weekly Checklist M3	Weekly Checklist	Incubate BHI Subculture controls Freezer boxes IC3 Weekly Checklists x3	Weekly Checklist	Tributyrin Optochin Bile Solubility MR-VP Blacta βCARB Bile esculin Weekly Checklist Wellcolex – biweekly	Eyewash Stations QUAD / Screens KB / Etest ID / Sensi cards Walk-in Fridge/Freezer Purified Water Count Weekly Checklist TREK Panels
Monthly			Waterbath Cleaning GeneXpert		Strep grouping	Bacti Serology Parts Cleaning Densichek Cleaning *S. aureus* 8610 sub
Bi-Annual			Defrost / Clean MIFR		Emergency Shower **Quarterly:** Autoclave Maintenance	Defrost/Clean -MIFA /-MIFC
When use	Germ Tube Acridine Orange String Test Ornithine	Indole	Tube Coagulase	Oxgall Agar Cornmeal Agar Calcofluore White Stain Modifed ZN Stain ZN Stain Acridine Orange		Saline / Tips
On Receipt				Fungal Media API 20C	Media & Reagents QC of GMP media	

OUT-OF-RANGE RESULTS:

1. Out of range results will be flagged in RED immediately and TQC will bridge to a "Corrective Action" window.
2. Choose an "Action ID" from the drop-down list.
   Note: Remember to choose an action beginning with "M_"
   a. If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the QC parameter that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order



   b. If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC
3. Enter a reason in the comments section and click "OK"
4. Verify and save your results
5. Inform QA or charge technologist of all out-of-range results

APPENDIX I - Bacteriology QC Bench Workflow

Daily

1. Read and document results of QC testing through LIS worklist "Media on Receipt"
2. This worklist will show all media/reagents/etc that need to be QC'd
3. Go to walk in fridge and retrieve any media, reagents, kits, or panels that need QC to be done; they will be found on tray on left hand side of fridge
4. New media should be already registered in TQC by the technicians
5. If needed, prepare labels for new media as per Printing QC Labels Procedure.
6. Prepare inoculum as required and set up QC as needed for the items
7. Subculture ATCC control strains according to Maintenance of Isolates Schedule Table.
8. Perform other daily QC Bench tasks as follows:

(a) Mondays (Tuesday if Monday is a Holiday)

KB Disc and Etest Weekly QC

1. On Thursdays, all of the necessary media and materials are assembled and labelled in advance for the following week's QC. Everything is placed in the white QC bucket and put in the walk-in fridge on the designated QC shelf.
   All of the labels required to perform the tasks for weekly QC have been prepared in advance and are found in blue folder.
   These can be reprinted from the links below using Avery 5167 labels:
   QC weekly KB, Etest, Trek labels
   QC weekly Tuesday set up, CO2 and ANO2 sub labels
   QC weekly Vk 2, TSA subs labels
2. Make the appropriate McFarland suspensions as per Kirby Bauer and E-Test tables.
   Label tubes as follows:

For Disc diffusion and Etest
14 Saline Tubes
Pa. 27853
Sa. 29213
Sa 700698
Sa 700699
Ec N10-505
Kp 1706
Kp 1705
Ec. 25922
Ef 29212
Hi. 49247
Sa. 25923
Se. 12228
Ss. 15305
Sp. 49619

For Vitek 2 QC
11 Saline Tube
Ec. 25922
Ec. 35218
Pa. 27853
Ef 29212
Ef 51299
Sa. 29213
Sa. 29213
Ef 29212
Sa. BAA1026
Sa. BAA976
Sa. BAA977

3. With the prepared suspensions, use the Kirby Bauer and E-Test tables to set up appropriate KB, e-test and ROSCO tests.

4. For *H. influenzae* ATCC 10211 monitor for growth on chocolate agar only

5. Set up Vitek2 cards and sub-culture purity plates. For Vitek QC set up, see Vitek ManualQuality Control Section

Tuesdays

1. Materials required:

Item	Amount
Sterile tubes	10
Vitek saline	1
MHB	1
Tributyrin	
BHI plate	2
Conical tube	2
BE	1
BA	1
Prolex kit	
Optochin	
VP reagents	

2. Prepare the following labels, if needed, as per Printing QC Labels Procedure using the "QC media on Receipt" worklist from TQC:

Test	Organism	Media
Bile Esculin	*E. faecalis* ATCC 29212	BE
Bile Esculin	*S. pyogenes* ATCC 19615	BE
Opt	*S. pneumoniae* ATCC 6303	BA
Opt	*S. sanguis* ATCC 10556	BA
Prolex	*S. pyogenes* (Group A) ATCC 19615	Tube
Prolex	*S. agalactiae* (Group B) ATCC 12386	Tube
Prolex	*S. equi ssp. equi* (Group C) ATCC 9528	Tube
Prolex	*Streptococcus* Group F ATCC 12392	Tube
Prolex	*S. equisimillis* (Group G) ATCC 12394	Tube
Prolex	*E. faecalis* ATCC 29212	Tube
Tributyrin	*M. catarrhalis* ATCC 8176	Tube
Tributyrin	*N. gonorrhoeae* ATCC 43069	Tube
VP	*Streptococcus* Group F ATCC 12392	Tube
VP	*S. pyogenes* ATCC 19615	Tube

APPENDIX II - Ordering a New QC ORGANISM in TQC

As new media, reagents, kits or methodologies are added to the list of items needing QC in Microbiology, it may be necessary to order **new** ATCC organisms for our stocks in order to test these items. First check QC Organisms List to ensure we don't already have the ATCC strain in our stock. If not, follow the instructions below for adding **new** ATCC strains to our list. Each one will be entered in TQC as a new control and then frozen in triplicate in the appropriate QC storage box. The technologist in charge will ask the LIS officer/TQC super user to enter in a new ATCC # and do a set-up of the new procedure in TQC.

You must pick which QC study freezer box the organism will be stored under
QCMON Organisms are subbed monthly from the freezer and used regularly
QCKIT Organisms are subbed as needed from freezer and used for QC of kit
QCNR Organisms are ATCC strains that are used infrequently

You may also pick a QC study if the organism will be subbed regularly:
QCANO2 ANO2 dependent organisms are subbed Mon/Wed/Fr
QCCO2 CO2 dependent organisms are subbed Mon/Wed/Fri.
QCMSC Organisms are subbed Monday
QCFSC Organisms are subbed Friday
QCSLA Organisms are subbed monthly to NA slants.

You may also pick a QC study if the organism will be used for weekly QC:
QCMSU Organisms are used on Mon. for QC of antibiotic disc, E-test.
QCTSU Organisms are used on Tue for QC of ID discs, reagents, etc.
QCVT2 Organisms are used on Mon for QC of Vitek N-213, P-567 and P-580.

You may also pick a QC study if the organism has special uses:
QCANT Organisms are used for QC of antisera.
QCMED Organisms are used to test media that must be QC as required by CLSI

1. Sub-culturing organisms:
   ~ Use the labels to subculture the organism to the appropriate media.

2. Generate Freezer labels for the organisms:
   ~ Enter in SoftStore. See Ordering New QC ORGANISMS in Soft procedure for entering ATCC strains into SoftStore.

3. Enter freezer vial location into Softmic work card:
   ~ On the back of the Softmic work card and "F9". FRZ "F9" COM "F12"
   ~ Enter the appropriate freezer information by wanding the freezer labels
   ~ Enter the item(s) that this particular organism is used for under COM (i.e. KB, etc.)
   ~ Enter the accession number(s) of duplicates of this ATCC strain if they have been generated for QC of other items. Refer to these as clones (i.e. clone is G0262007 for Denim Blue)

4. Update -QC Organisms List.

APPENDIX III - Order Entry for New QC TESTS

When new media, reagents, kits or methodologies are added to the list of items needing QC in Microbiology *and* we already have the ATCC strain in our QC stocks, discuss with the LIS officer/TQC super users to set-up the QC tests as needed.

APPENDIX IV - Printing QC Labels Procedure

1. Login to TQC
2. Click "Tools" on the top toolbar and choose "Print Labels"
3. Enter the Lot# or QC item in the Search Window and click "Search"
4. Choose type of label to be printed ie: Lot Labels, Parameter Control Labels etc.
5. Click "Network Printer" and search for the printer to be used from the drop down list
6. Click "Run"
7. If multiple copies of labels are needed, you can edit the label number using the arrows in the copies section or type in the desired number

In LIS the two worklists most commonly used by the QC bench are:

- **QCMED (QC media on receipt)** on the receiving worklist for new media/reagents
- **VT-QC (Vitek QC)** on the QC/Sendout worklist for all other routine QC tasks

In TQC the two worklist most commonly used by the QC bench are:

- **M_QC_BENCH (QC bench QC worklist)**
- **M_QCRECV (QC bench receiving worklist)**

APPENDIX V - Bench Quality Control Documentation in LIS/TQC

Daily Bench QC for TQC

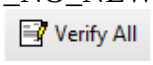
Daily bench QC is to be done on all benches and must be acceptable prior to testing patient samples. These QC items include reading temperatures of heating blocks/waterbaths, instrument maintenance, QC of media, catalase, oxidase, staphylococcus slide agglutination etc.

To document the QC results into LIS/TQC, follow the steps below:

Entering Results through LIS	Entering Results through TQC
1) Open Resulting Worklist in LIS 2) The worklist will bridge to TQC and generate all the pending orders 3) Double click on the selected order or click "Open" 4) Enter in the results. Items that are acceptable will display in Green and results Out-of-Range will display in Red 5) If all results are acceptable, go to Step 7 6) If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section a) If "M_QC_OUT_REPEAT" is chosen: it will prompt a repeat QC order for the item that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order b) If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC 7) Click "Verify" and "Save"	1) Login to TQC 2) Access your pending results through the "Resulting worklist" 3) Under worklist ID enter "M_" click "Search" 4) Find the associated worklist and double click or click "Run Worklist" 5) The worklist will generate all the pending orders 6) Double click on the selected order or click "Open" 7) Enter in the results. Items that are acceptable will display in Green and results Out-of-Range will display in Red 8) If all results are acceptable, go to Step 10 9) If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section a) If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the item that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order b) If "M_QCOUT_NO__NEW_ORDER" is chosen: it will not prompt any repeat orders for QC 10) Click "Verify All" and "Save"

Note: If there are components attached (ie: drugs on a panel, etc.) a window will pop-up to select/verify the lot#'s and expiry dates

To enter temperatures for heating blocks or instruments:

1. Through TQC or the Resulting Worklists select the order for the heating block or instrument
1) Double click or select "Open" to access "Result Entry"
2) Type in the temperature recorded in the "Expected Results" field
3) If the result is acceptable it will display in Green, results out-of-range will display in Red
4) If all results are acceptable, go to Step 6
5) If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section
   a) If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the QC parameter that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order
   b) If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC
6) Click "Verify All" 

and "Save" 

7) The order should status should change to 

upon completion. R-resulted, N-in range and V-verified.
8) To remove completed QC orders from the worklist, click refresh at the bottom of the screen

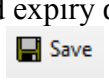
As-Needed QC for TQC

For QC items that are only performed when a test is ordered for a patient.

A. For tests that are associated with the "Media Comment" screen e.g. ALA, Germ tube, etc.
At the "Media Comment" Screen:

1. Pick the test from the keypad eg: ^ALA
2. When finished documenting sample, save the order.
3. A QC order should generate on your bench's worklist (you may need get out and go back into your worklist to see the new order)
4. Double click on the item
5. Perform the necessary QC tests
6. Enter in the results in the "Expected Results" field. Items that are acceptable will display in Green and results Out-of-Range will display in Red
7. If all results are acceptable, go to Step 9
8. If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section
    a. If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the QC parameter that was out-of-range, use the check boxes to add additional QC parameters if needed.
    b. If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC
9. Click "Generate Order" to create a new QC order
10. Click "Verify All"  and "Save" 

B. For tests that are usually NOT associated with the "Media Comment" screen ie: B-lac, etc

1. Log in to TQC
2. Open the Orders tab on the main page of TQC → click "Order Entry"
3. To generate a new order, select the "New Order"  icon at the top left corner (looks like a white sheet of paper)
4. Search for the item using the search window
5. To filter for only micro items use "M_" or use the "Item Type"
6. The number of orders to generate can be changed but the default is set to one order
7. Click "Generate Order"
8. It will then bridge to "Result Entry"
9. Enter results, then click "Verify All" 
10. If there are components attached (ie: drugs on a panel, etc.) a window will pop-up to select/verify the lot#'s and expiry date
11. Click "Save" 

TQC for the QC BENCH

Daily Duties

1. Login to TQC
2. Open the "Results" tab and click on "Resulting Worklist"
3. In the Worklist ID at the top enter "M_" for micro worklists
4. Click "Search for Worklist"
5. Click M_QCBENCH for daily worklist
6. To enter results on an order double click on the desired order or click "open"
7. Enter results into the "Results" field
8. If the result is acceptable it will display in Green, results out-of-range will display in Red
9. If all results are acceptable, go to Step 11
10. If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section
    a. If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the QC parameter that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order
    b. If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC
11. Click "Verify All" 

and "Save" 

12. If there are components attached (ie: drugs on a panel, etc.) a window will pop-up to select/verify the lot#'s and expiry dates
13. The order should status should change to 

upon completion. R-resulted, N-in range and V-verified.
14. To remove completed QC orders from the worklist, click refresh at the bottom of the screen

New Lot Numbers/Shipments

On receipt of any new lots of media, reagents or panels, the technicians will enter the new lots numbers into TQC and give the new items to the technologist on the QC bench. The QC results from the new items will be entered into TQC once complete.

1. Login to TQC
2. Open the "Results" tab and click on "Resulting Worklist"
3. In the Worklist ID at the top enter "M_" for micro worklists
4. Click "Search for Worklist"
5. Click M_QCRECV for QC receiving bench worklist
6. To enter results on an order double click on the desired order or click "open"
7. Enter results into the "Results" field
8. If the result is acceptable it will display in Green, results out-of-range will display in Red
9. If all results are acceptable, go to Step 11
10. If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section
    a. If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the QC parameter that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order
    b. If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC
11. Click "Verify All"  and "Save" 
12. If there are components attached (ie: drugs on a panel, etc.) a window will pop-up to select/verify the lot#'s and expiry dates
13. The order should status should change to  upon completion. R-resulted, N-in range and V-verified.
14. To remove completed QC orders from the worklist, click refresh at the bottom of the screen

APPENDIX VI - SOFT for TotalQC

1. Technicians will register all items needing QC in SoftTotalQC when received.

To register an item/media for QC it can be done under "Lot Records" in SoftTotalQC

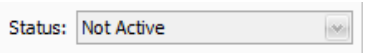
a) Open Lot records under Inventory tab

b) Click on "NEW"  to create a new lot record

c) Use the Search window to find the item using M_ and/or filtering by Type

d) Highlight the desired item and click "OK"

e) Required fields are highlighted in RED and MUST be entered in order to save the record

f) Change the Status to "Active" using the drop down menu 

g) Save the record

h) If multiple lots are "Active", a pop-up may appear asking to "Close the other Record(s)", select "No"

i) It will then bridge over to "Result Entry"

j) The Inventory Checklist will be completed by the person receiving the item(s)/media(s)

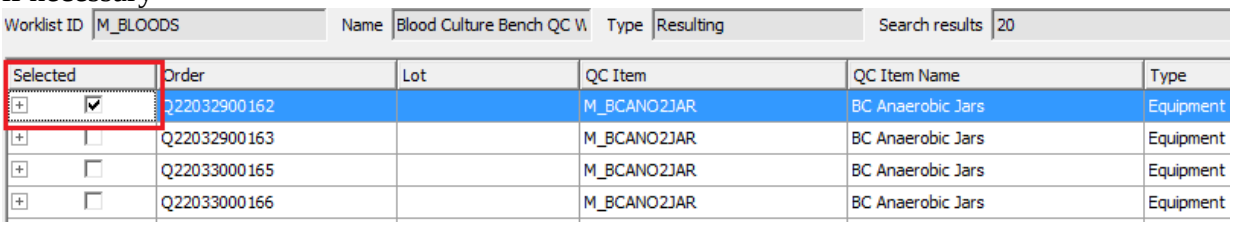
k) After results are entered click "Verify All" 

and "Save" 

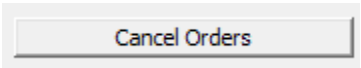
2. Reagents, media or panels that have QC done (other than items that are tested "on receipt" only), **must** have an **active** lot in order for the QC to be generated. Note also that when an active lot expires, the QC program inactivates it and the QC tests will not generate on this lot. When time permits, check that these reagents, media or panels have active updated lot #. Changing the active lot may result in the generation of duplicate QC procedures (the old lot and the new lot). Cancel the duplicate procedures.

To Cancel an Order in TQC

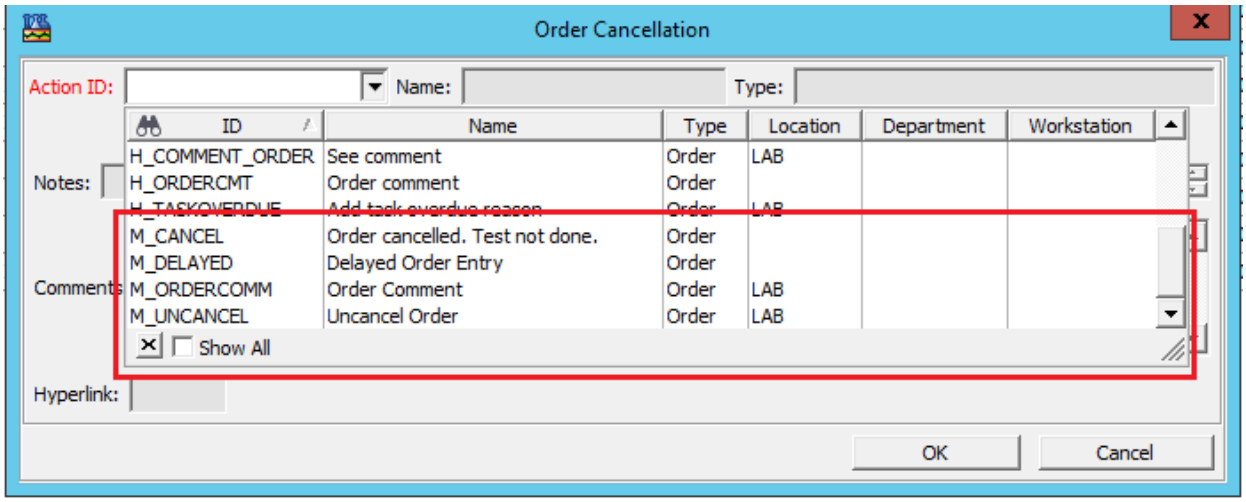
- Select the order you wish to cancel by clicking the check box. Multiple orders can be selected if necessary



- Select "Cancel Orders" from the options on the right hand side



- Select an Action ID from the drop down list. Scroll down to the "M_" actions at the bottom



- Choose "M_CANCEL". Then Click OK. Comments can be made if needed
- A confirmation window will pop-up. Select Yes

3. Report all QC exceptions to the QA Technologist or a charge technologist to ensure the appropriate action is taken.

4. Unusual items for which QC has not been set up for should be brought to the attention of the LIS officer or TQC super-users.

5. Separate shipments of the same Lot # are treated as new lots and must have QC performed again.

6. Vitek panels must be entered in the Vitek QC program when received as well as being entered in to TQC. Vitek sensitivity panels must have a current active lot entered in TQC in order to generate the weekly VT sensitivity QC. Vitek lots that are no longer in stock should be deleted from the Vitek QC program (under QC lot maintenance).

7. When time permits, check if new lots of reagents, kits, etc. have arrived that have not been brought to the attention of the QC bench. Lists of reagents, media and panels that are to have QC performed are posted by the walk-in refrigerator.

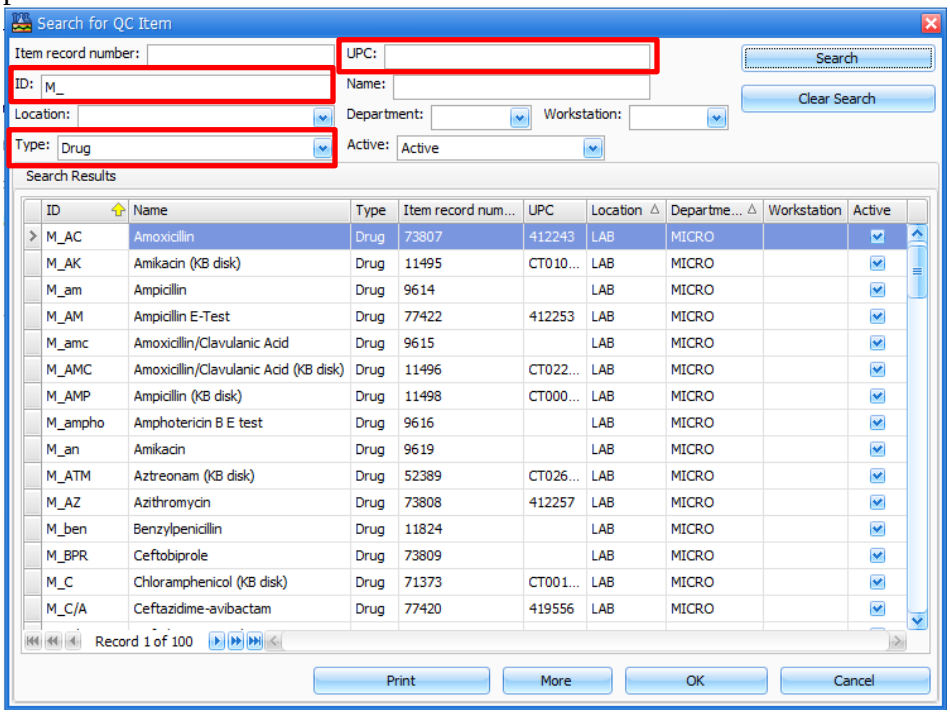
APPENDIX VII - Registering Antibiotics

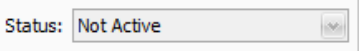
Registering Antibiotic Discs

Note: Technicians are to be entering all antibiotics into TQC prior to giving them to the QC bench.

If not present in TQC, follow the instructions below:

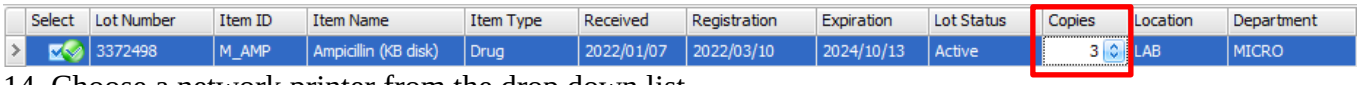
1. Login to TQC
2. Open Lot records under Inventory tab
3. Click on "NEW"  to create a new lot record
4. Use the Search window to find the item using "M_" and/or filtering by Type "Drug" OR enter the product number in as the UPC code



5. Highlight the desired item and click "OK"
   Note: Use the ID's that are in all capital letters or have KB disk ie: M_AMP not M_am
6. Required fields are highlighted in RED text and MUST be entered in order to save the record
7. Change the Status to "Active" using the drop down menu 

8. Save the record
9. If the lot number already exists, a pop-up will appear asking if the lot # is correct; if it is correct click "OK"

10. If multiple lots are "Active", a pop-up may appear asking to "Close the other Record(s)", select "No"
11. To print labels, click on the print labels  icon on the top toolbar
12. Choose Lot Labels
13. The number of labels can be changed under the copies heading by using the arrows or entering the number desired



Select	Lot Number	Item ID	Item Name	Item Type	Received	Registration	Expiration	Lot Status	Copies	Location	Department
✓	3372498	M_AMP	Ampicillin (KB disk)	Drug	2022/01/07	2022/03/10	2024/10/13	Active	3	LAB	MICRO

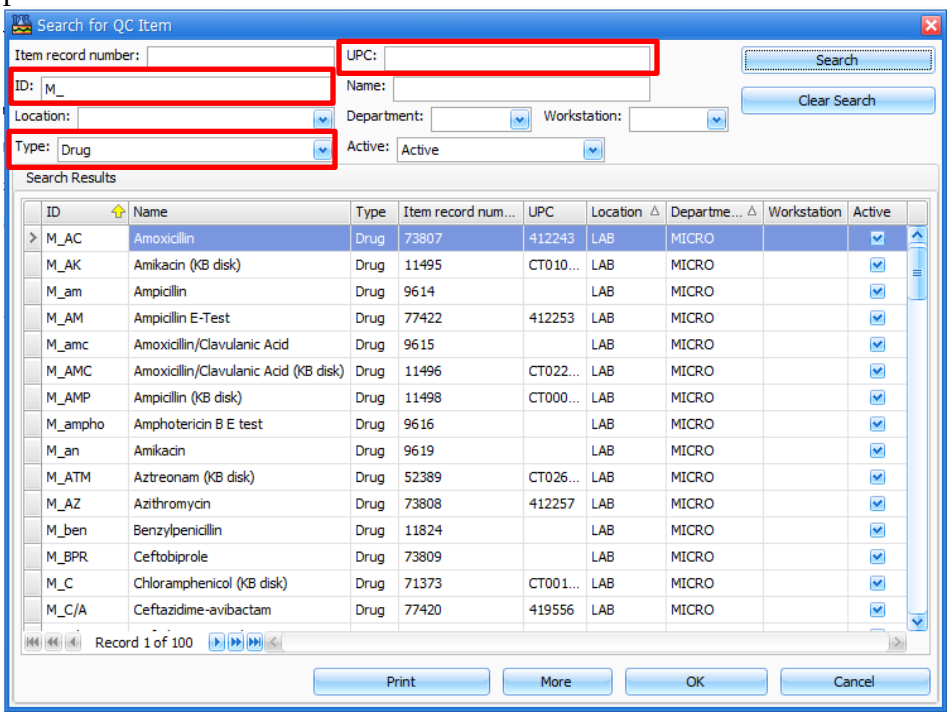
14. Choose a network printer from the drop down list
15. Click "Run"
16. Place cartridges with their labels (to be affixed to the cartridges when put into use.) in a polybag. Put no more than 5 cartridges in each bag.
17. Check the inventory in the freezer to see if there are any other bags of that particular antibiotic in stock. If so, and they will outdate before the new lot place the bag behind the currently used box in the freezer. Use an elastic band to group different lot numbers together.
18. Retrieve the green index card from the clear envelope on the Antibiotic freezer that is labeled "These Items Have Already Been Ordered" and place it back in position behind the yellow index card inside the freezer.

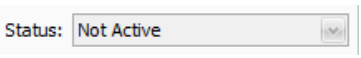
Registering E-test Antibiotics

Note: Technicians are to be entering all antibiotics into TQC prior to giving them to the QC bench.

If not present in TQC, follow the instructions below:

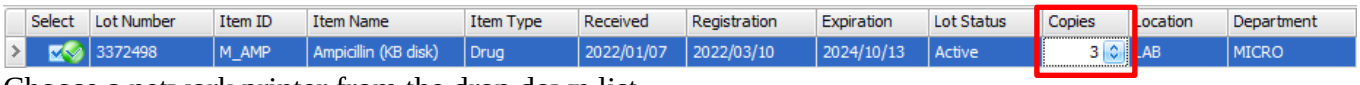
1. Login to TQC
2. Open Lot records under Inventory tab
3. Click on "NEW"  to create a new lot record
4. Use the Search window to find the item using "M_" and/or filtering by Type "Drug" OR enter the product number in as the UPC code



5. Highlight the desired item and click "OK"
   Note: Use the ID's that are in all capital letters or have E-test ie: M_AM not M_am
6. Required fields are highlighted in RED text and MUST be entered in order to save the record
7. Change the Status to "Active" using the drop down menu 

8. Save the record
9. If the lot number already exists, a pop-up will appear asking if the lot # is correct; if it is correct click "OK"
10. If multiple lots are "Active", a pop-up may appear asking to "Close the other Record(s)", select "No"
11. To print labels, click on the print labels  icon on the top toolbar
12. Choose Lot Labels

13. The number of labels can be changed under the copies heading by using the arrows or entering the number desired



Select	Lot Number	Item ID	Item Name	Item Type	Received	Registration	Expiration	Lot Status	Copies	Location	Department
☑	3372498	M_AMP	Ampicillin (KB disk)	Drug	2022/01/07	2022/03/10	2024/10/13	Active	3	LAB	MICRO

14. Choose a network printer from the drop down list
15. Click “Run”
16. Etest strips come in 3 different types of packaging: individually, 100 foam pack and multipack strips.
17. For the individual ones, you need to print a barcode label and affix to each. Wrap an elastic band around 5 strips and place them in the polybag. Affix the “date received” label to the outside of the polybag. Upon use, remove 1 set of 5 strips and place into the large conical tube in the Working Etest Rack
18. For the 100 foam pack, aseptically distribute the strips into 4 sterile conical tubes. Print 4 barcode labels. Place the conical tubes and loose labels in the polybag. Affix the “date received” label to the outside of the polybag. Upon use, 1 conical tube and 1 barcode label will be removed from the polybag. The contents of the conical tube will be dispensed into the large conical tube in the Working Etest Rack. The barcode label will be placed inside the tube as well.
19. For the multipack strips, affix one barcode label to each group of the bubble pack and place in a polybag. Affix the “date received” label to the outside of the polybag. Upon use, one strip will be cut off and placed in the large conical tube in the Working Etest Rack.
20. Check the inventory in the freezer to see if there are any other bags of that particular antibiotic in stock. If so, and they will outdate before the new lot place the bag behind the currently used bag in the freezer. Use an elastic band to group different lot numbers together.
21. Retrieve the orange index card from the clear envelope on the Antibiotic freezer that is labeled “These Items Have Already Been Ordered” and place it back in position behind the orange index card inside the freezer.
22. Retrieve the orange index card from the clear envelope on the Antibiotic freezer that is labeled “These Items Have Already Been Ordered” and place it back in position behind the orange index card inside the freezer.

APPENDIX VIII - Rarely Used Antibiotic

For a Complete list of antibiotic inventory see: Kirby Bauer and E-test Purchasing and Inventoryforms

RARELY USED DISKS

AZITHROMYCIN	**AZM**	**FUCIDIC ACID**	**FD**	**NORFLOXACIN**	**NOR**
CARBENICILLIN	**CAR**			**OFLOXACIN**	**OFX**
CEFACLOR	**CEC**	**IMIPENEM**	**IPM**	**POLYMYXIN B**	**PB**
CEFIXIME	**CFX**	**KANAMYCIN**	**PRL**	**PIPERACILLIN**	
			K	**SULPHAPHURAZOLE**	**SF**
CEFOTETAN	**CTT**	**LINEZOLID**	**LZD**	**TEICOPLANIN**	**TEC**
CEFTIZOXIME	**ZOX**	**METRONIDAZOLE**	**MTZ**	**TICARCILLIN**	**TIC**
CHORAMPHENICOL	**C**	**MEZLOCILLIN**	**MEZ**	**TIC/CLAV (Timentin)**	**TIM**
CLARITHROMYCIN	**CLR**	**MINOCYCLINE**	**MH**	**TRIMETHOPRIM**	**W**
COLISTIN	**CT**	**MOXIFLOXACIN**	**MXF**		
FOSFOMYCIN	**FOS**	**NEOMYCIN**	**N**		

FOR DAPTOMYCIN AND TELITHROMYCIN-SPECIAL ORDER ONLY

RARELY USED ETEST

AMIKACIN	**AK**	**CLARITHROMYCIN**	**CH**	**OXACILLIN**	**OX**
AMPICILLIN	**AM**	**CLINDAMYCIN**	**CM**	**SULPHAMETHOXAZOLE**	**SX**
AZITHROMYCIN	**AZ**	**DOXYCYCLINE**	**DC**	**TETRACYCLINE**	**TC**
CEFOTETAN	**CN**	**ERYTHROMYCIN**	**EM**	**TICARCILLIN**	**TI**
CEFOXITIN	**FX**			**TIC/CLAV**	**TLc**
CEFTIZOXIME	**CZ**	**IMIPENEM**	**IP**	**TIGECYCLINE**	**TGc**
		TOBRAMYCIN	**TM**		
CEPHALOTHIN	**CE**	**MEROPENEM**	**MP**		
CHLORAMPHENICOL	**CL**	**METRONIDAZOLE**	**MZ**		
CIPROFLOXACIN	**CI**	**MOXIFLOXACIN**	**MX**		
		NETILMYCIN	**NC**		

FOR GENTAMYCINAND STREPTOMYCIN- SPECIAL ORDER ONLY

QC performed on rarely used antibiotics must be recorded in the LIS to be reviewed by seniors before finalized. In your workcard under the appropriate media, use the TESTS keypad and select **{RARE** to populate information needed for QC purposes. Fill in all areas.

Rarely used Antibiotic:	ATCC QC strain used:	
Lot#:	ATCC expected value:	QC Valid?
Expiry date:	ATCC QC strain measured value:	

APPENDIX IX - Vitek 2 Weekly Susceptibility QC

1. Labels saline tubes and purity plates using the appropriate labels from the file folder

2. Label one saline tube for each of the 9 ATCC strains listed below:
   a) *E. coli* 25922
   b) *E. coli* 35218
   c) *P. aeruginosa* 27853
   d) *E. faecalis* 29212
   e) *E. faecalis* 51299
   f) *E. coli* 35218
   g) *S. aureus* 29213
   h) *E. faecalis* 29212
   i) *S. aureus* 29213

3. Label 9 Blood agar plates with ATCC strain labels. Put a dividing line on each plate. Mark one half of each plate 1 and the other half 2 to indicate Vitek Machine 1 and Vitek Machine 2.

4. Check the lot numbers of the AST N391, AST GP580, and the AST GP67 cards in the display fridge and on the media cart to ensure that they are the same as those being used in the blood culture area. Check the sticker on the box that shows the date that the box was received. Jot down the date on the sticker. It is possible that there are multiple shipments of the same lot number. The first time a lot is QC'd it is referred to as isolate 1. Any subsequent shipments of the same lot number are identified as isolate 2, 3, 4 etc. respectively. The sticker date will help identify which shipment they belong to and which isolates they are. In order to ascertain that the correct lot numbers are in use, take one of each of the cards types and the dates you have jotted down for each with you to the Vitek 2 computer.

5. At the Vitek 2 instrument, click on Utilities.
   - Click "Quality Control"
   - Click "Load List"
   - Click "Test Type" column header. A box will drop down with the various card types.
   - Choose the card types to be tested. To highlight more than one card type, hold down the CTRL key while clicking and highlighting each card type.
   - Click "Apply"
   - Click "Sort By" "Test Type" (in lower left hand corner of screen.) (Items in the load list will be in order)

- Click "Lot Number" column header. A box will drop down with the various lot numbers. To highlight more than lot number, hold down the CTRL key while clicking and highlighting each lot number. (This is where you refer to the dates jotted down for each lot to ensure you have QC the correct shipment.)
- Click "Apply"
- Click  icon to print selected load list.

6. Make 0.5 McFarland suspensions of each ATCC strain using the Densichek.

7. Label one Vitek 2 smart carrier QC Machine 1 and one Smart Carrier QC Machine 2.

8. Place the inoculated Vitek 2 salines in positions 1, 3, 5, 7, 9, 11, 13 of the first smart carrier as outlined in the loadlist. Place an empty Vitkek 2 tube in positions 2, 4, 6, 8, 10, 12 and 14. (There is a template on the Smart Carrier Station near the QC bench. It outlines the position in the smart carrier in which to place each inoculum tube.)

9. Place the remaining two inoculated Vitek 2 salines in the second carrier with the corresponding empty Vitek 2 tubes as per the template.

10. Remove all lids from tubes.

11. Load the first Smart Carrier onto the Smart Pad.

12. Use the "Vitek 2 Weekly Sensi Template" to wand the barcode for the Accession ID for each organism as outlined in the load list. (It is probably easier to use the wand in the "Handheld Mode" for this purpose.) Note: The Smart Pad automatically defaults to Isolate 1, but you need to check the Load List printout to see if there are any lots that are not "isolate 1". If there are, you must arrow up and put in the appropriate isolate number. Wand the barcode on the sensitivity card. Do this for each isolate.

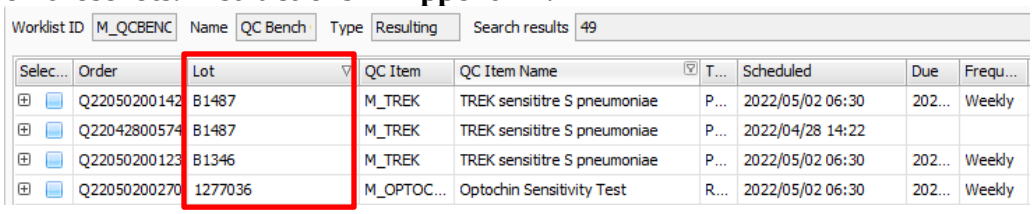
13. Once complete, press F3 on the smart pad and ensure that everything is correct i.e. according to the load list.

14. Put the 2 smart carriers in each of the Vitek instrument readers according to the label on each.

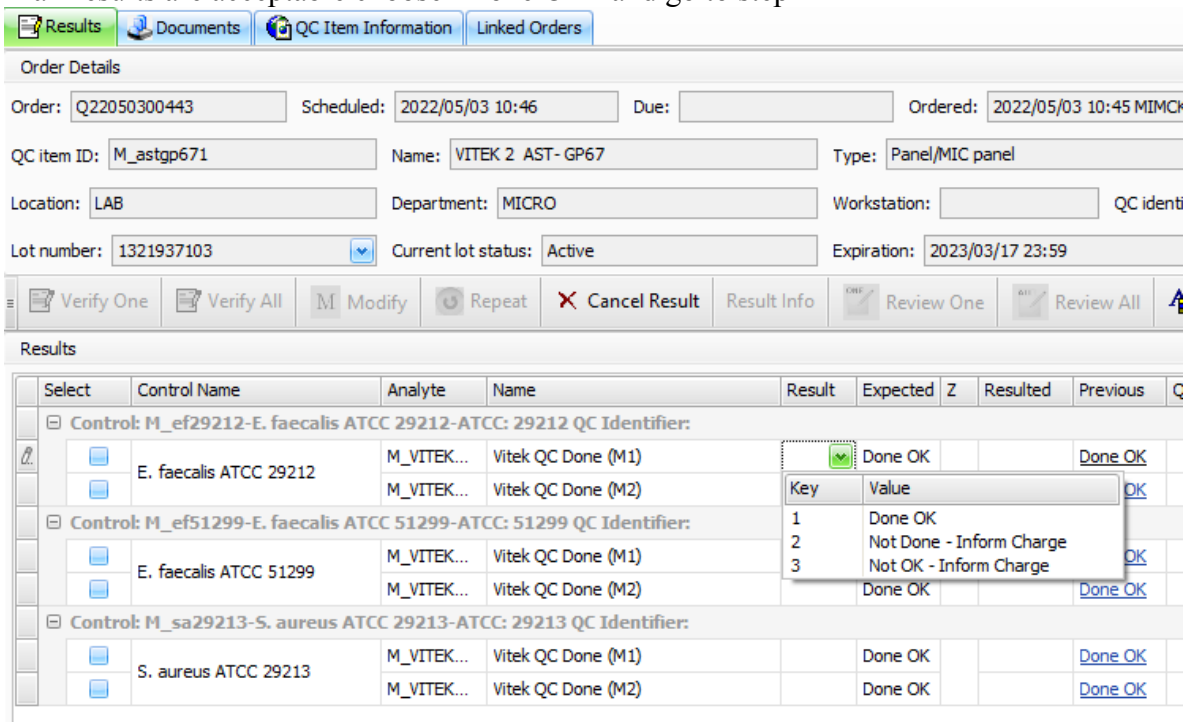
15. Once the cards have finished processing, and the smart carriers return to the loading dock, make the appropriate purity plates from the sensitivity inoculum tube and then discard it.

16. Exchange the labels of the two smart carriers and repeat steps 7-16.

17. On the following day record your results in TQC for each Vitek panel set-up under the appropriate lot number.
NOTE: If multiple lot numbers are "ACTIVE" in TQC ensure you are entering under the correct one. The other orders can be cancelled if QC is not being done on those lots. Instructions in Appendix VI



18. If all results are acceptable choose "Done OK" and go to step 21



19. If results are out-of-range, a "Corrective Action" window will appear and a corrective action must be selected. A description of the problem can be entered in the comments section
    - If "M_QCOUT_REPEAT" is chosen: it will prompt a repeat QC order for the QC parameter that was out-of-range, use the check boxes to add additional QC parameters if needed. Click "Generate Order" to create a new QC order
    - If "M_QCOUT_NO_NEW_ORDER" is chosen: it will not prompt any repeat orders for QC. Click "OK" to continue.
20. Click "Verify All" 

and "Save" 

APPENDIX X – MEDIA Requirements On-Receipt for QC Bench

Inventory Technician: Give the following to the QC bench when received:

# of Plates	Media	# of Plates	Media
3	EBM, Aesculin Agar W/ Chloramphenicol, Gentamicin* _Hlk453076252	**2** **3**	Mueller Hinton Agar – Large Muller Hinton Agar – Small
3	BHI Agar	**3**	Mueller Hinton Agar w/ 4% Salt
3	BHIM Agar W/ ccg W/ 5% Sheep Blood*	**3**	Mueller Hinton Agar w/ 4% Salt, 6 mcg oxacillin
3	BHI Agar W/ Casein	**3**	Motility Tubes
3	BHI W/ Gent 500, BHI W/ Strep 2000	**1**	MR-VP
3	BHI Agar W/ 6 mcg Vanc	**1**	Reasoners 2A Agar (R2A)
1	Bile Esculin Plate	**3**	Visa Isolate Agar
3	Campylobacter Agar		
2	Candida Plus Agar		
4	Carrot Broth		
3	Chocolate Agar		
3	Chromogenic Brilliance VRE Agar **		
3	Chromogenic MRSA Denim Blue **		
3	Chromogenic Urine Biplate, UTI **		
3	Haemphilus Selective Agar		
3	Haemophilus Test Medium Agar		**GMP Media**
3	Inhibitory Mold Agar	**1 bag**	Chocolate Agar
3	Kanamycin / Vancomycin Agar	**1 bag**	Tryptic Soya Agar
3	Macconkey Agar w Cefpodoxime, ESBL	**1 bag**	Inhibitory Mold Agar *
3	Macconkey Agar With Colistin CTCZ	**1 bag**	Fastidious Anaerobe Agar
3	Macconkey Agar Sorbitol, SMAC		
3	Martin Lewis Agar		

***Please forward to Mycology**
**** Light sensitive: place plates in a Brown Bag**

APPENDIX XI – REAGENT Requirements On-Receipt for QC Bench

Inventory Technician: Give the following to the QC bench after registration in TQC and perform QC when received:

Acridine Orange	**James reagent**
ALA disks	**Kovacs reagent**
Aminopeptidase (Bactident)	**LAP discs**
API 20E strips	**Lactophenol Blue Stain***
API 20NE strips	**Optochin**
API NH strips	**Oxidase droppers**
BLacta	**Phadobact kit**
BCarba	**PYR kits**
Bacitracin discs	**Saline (3mL & 0.5mL)**
Catalase (hydrogen peroxide)	***Salmonella* serology**
Cefinase discs	***Shigella* serology (Remel)**
Cryptococcal Antigen Latex kits	***Shigella* serology (Wellcolex)**
Denka kits	**Staph – Pastorex kits**
Bile Solubility (deoxycholate) droppers	**Strep group Prolex Reagents 1,2,3, ABCDFG**
***E.coli* 0157 Test kits**	**TREK Panels**
Eosinophil Stain	**Tributyrin discs**
FAB Broth	**Tube coagulase**
Ferric Chloride	**VITEK cards**
Fungi Fluor stain*	**Vitek MS Matrix**
Horse serum	**Vitek MS Formic Acid**
Indole spot reagent	**ZN Stain kits**

***Please forward to Mycology**

Note: ALL antibiotics and E-tests must be given to QC bench on receipt after registration in TQC

Record of Edited Revisions

Manual Section Name: Quality Control Manual

Page Number / Item	Date of Revision	Signature of Approval
Annual Review	May 2, 2002	Dr. T. Mazzulli
Annual Review	May 12, 2003	Dr. T. Mazzulli
Annual Review	May 14, 2004	Dr. T. Mazzulli
Annual Review	May 12, 2005	Dr. T. Mazzulli
Annual Review	July 23, 2006	Dr. T. Mazzulli
Pipette check expected ranges	October 10, 2006	Dr. T. Mazzulli
Media to be sent for QC Appendix VI – revised	April 26, 2007	Dr. T. Mazzulli
Reagent to be sent for QC – appendix VII - revised	April 26, 2007	Dr. T. Mazzulli
Added – Appendix II Ordering QC organisms in Soft	April 26, 2007	Dr. T. Mazzulli
Added – Appendix III Printing QC Labels	April 26, 2007	Dr. T. Mazzulli
Refer Vitek QC to Vitek Manual	April 26, 2007	Dr. T. Mazzulli
Added – Appendix IV Order Entry for new QC organisms	April 26, 2007	Dr. T. Mazzulli
Appendix X – Weekly Susceptibility QC procedure added	April 26, 2007	Dr. T. Mazzulli
Annual Review	April 26, 2007	Dr. T. Mazzulli
Appendix X – Registering antibiotics procedure added	October 21, 2007	Dr. T. Mazzulli
Appendix X – Weekly Susceptibility QC procedure changed to Appendix XI	October 21, 2007	Dr. T. Mazzulli
Link to List of Antibiotics for QC	October 21, 2007	Dr. T. Mazzulli
Reagent, Kit QC procedure (page 19) - updated	October 21, 2007	Dr. T. Mazzulli
List of rarely used antibiotics added	October 21, 2007	Dr. T. Mazzulli
Annual Review	May 15, 2008	Dr. T. Mazzulli
Annual Review	May 15, 2009	Dr. T. Mazzulli
Annual Review	May 20, 2010	Dr. T. Mazzulli
Annual Review	May 26, 2011	Dr. T. Mazzulli
Updated culture media list for quality control Removed EV. Added VISA and Brilliance	May 26, 2011	Dr. T. Mazzulli
Updated Appendix XIII QC KB Antibiotic Inventory list	May 26, 2011	Dr. T. Mazzulli
Updated Table 1 – KB antibiotics list	May 26, 2011	Dr. T. Mazzulli
Updated Table 2 – KB antibiotics zone size	May 26, 2011	Dr. T. Mazzulli
Updated Antimicrobials MIC QC, modified into Table 3	May 26, 2011	Dr. T. Mazzulli
Updated Appendix VIII – list modified	February 28, 2012	Dr. T. Mazzulli
Updated Appendix IX – list modified	February 28, 2012	Dr. T. Mazzulli

Page Number / Item	Date of Revision	Signature of Approval
Updated registering of OXA and VANC screen plates	October 02, 2012	Dr. T. Mazzulli
Updated Bacteriology QC workflow	October 02, 2012	Dr. T. Mazzulli
Updated QC media list	October 02, 2012	Dr. T. Mazzulli
Annual Review	October 02, 2012	Dr. T. Mazzulli
Added ROSCO and TREK QC	October 16, 2012	Dr. T. Mazzulli
Annual Review	May 30, 2013	Dr. T. Mazzulli
Inserted proper headers, Updated UHN/MSH logo	October 2, 2014	Dr. T. Mazzulli
Annual Review	October 2, 2014	Dr. T. Mazzulli
Modify For *N. gonorrhoeae, H. influenzae and C. jejuni*: Preperation procedure p.6. Annual Review	March 24, 2015	Dr. T. Mazzulli
Update procedure	October 2, 2015	Dr. T. Mazzulli
Annual Review Removed chart to log QC of rarely used antibiotics and replaced with LIS documentation instructions. (Appendix VIII) Addition of yearly QC of GMP media (thioglycollate/ Trypticase Soya Broth). • Added to overview of QC chart. • Added organisms for QC with expected results in Organisms for media QC chart	January 16th, 2016	Dr. T. Mazzulli
Annual Review Updated full procedure. Remove TREK QC	February 5, 2016	Dr. T. Mazzulli
Rarely Used Antimicrobial Recording Chart added to appendix VIII – rarely used antibiotics, link added to table in antibiotic QC section Updated MSH logo in header	February 28, 2016	Dr. T. Mazzulli
C/T (Ceftolozane-Tazobactam) Etest added to Pseudo QC Remove Tigecycline from rarely used;	April 18, 2016	Dr. T. Mazzulli
REAGENT AND TEST KITS QUALITY CONTROL section added: lactophol blue Added Lactophenol blue to appendix list of reagents requiring QC on receipt.	June 7, 2016	Dr. T. Mazzulli
PRL KB moved to rarely used, removed from weekly set up.	August 19, 2016	Dr. T. Mazzulli
Annual Review *C difficile* 9689 ANO_2 Removed from QC organisms to	January 26, 2017	Dr. T. Mazzulli

Page Number / Item	Date of Revision	Signature of Approval
sub. *C difficile* removed from ANO2 control plate. Remove CXM (Cefuroxime) kb on ecoli. No longer in use. Removed Cefuroxime etest from rarely used list. No longer in stock. Moved TS (septra etest) from rarely used to weekly QC with e.coli ATCC.		
Addition of *Neisseria gonorrhoeae* ATCC 49226 in maintained QC organism list. Addition of ng49226 in e-tests to set up table.	February 21, 2017	Dr. T. Mazzulli
Addition of Vitek MS daily controls on daily QC for IC and BC bench added to LIS QC chart Addition of Daily Vitek MS controls to Stock Culture Sub-culturing schedule.	July 7, 2017	Dr. T. Mazzulli
Added result of Haze as acceptable for OX screen plate with *S.aureus* ATCC43387	September 25, 2017	Dr. T. Mazzulli
Addition of saline and FAB sterility testing upon receipt in reagent QC section.	December 29, 2017	Dr. T. Mazzulli
Minor format change	September 14, 2018	Dr. T. Mazzulli
Added Ceftobiprole (BPR) to Rarely used etest	November 02, 2018	Dr. T. Mazzulli
Trek Panels added to Reagents to be QC'd upon receipt. Added to Quality Review table for Vitek weekly QC	January 03, 2018	Dr. T. Mazzulli
Annual Review R2A Agar Added to media QC on receipt.	January 08, 2018	Dr. T. Mazzulli
Annual Review Rarely used Gatifloxicin kb and Etest archived, no longer required.	February 04, 2019	Dr. T. Mazzulli
Updates based on 2019 CLSI guidelines: pg 4-5 - added new ATCC strains of N. gonorrhoeae, E coli, K pneuomo for QC/schedule of stock s/c pg 19 - added Ecoli and K pneumo/Cefpodoxime to Table: Antibiotics to be Tested for KB QC	October 08, 2019	Dr. T. Mazzulli
Pg 15-22 • Replace E. coli 25922 with E. coli 35218 for AMC KB disk QC. • Replace E. coli 25922 with E. coli 35218 for TIM KB disk QC (rare antibiotic, QC not written in SOP). • Replace P. aeruginosa 27853 with E. coli 35218 for TZP KB disk QC.	October 20, 2019	Dr. T. Mazzulli

Page Number / Item	Date of Revision	Signature of Approval
• Replace P. aeruginosa 27853 with K. pneumoniae 700603 for C/T E-test QC. • Add K. pneumoniae 700603 to the monthly freezer sub schedule and weekly slant sub schedule. Pg 4-5 • NEW STEP: Add ampicillin KB QC to E. coli 35218 upon stock removal from freezer AND upon each weekly sub. • NEW STEP: Add cefpodoxime KB QC to K. pneumoniae 700603 upon stock removal from freezer AND upon each weekly sub."		
Annual Review Addition of weekly plate cultures of *Aspergillus brasiliensis ATCC 160404*	January 6, 2020	Dr. T. Mazzulli

Full document review included in all updates. Bi-annual review conducted when no revision had been made within 2 years.

Page Number / Item	Date of Revision	Edited by:
• Addition of Fastidious Anaerobic Agar to ORGANISMS FOR MEDIA QC AND EXPECTED RESULTS chart • Addition of Haemophylus influenzae B-lac- 10211 CO2 CHOC & Neisseria gonorrhoeae ATCC 43069(Weekly sub from the freezer) to schedule for subculture chart • Changed GMP media from QC Annually to QC for every new lot or shipment • Added Tryptic Soya Agar Lec/Tween 55 , Tryptic Soya Agar Lec/Tween , Tryptic Soya Agar, Brucella agar, IMA & Choc under GMP media ; in addition to expected result of <=100CFU for the TSA agars and IMA • Added GMP media under **MEDIA Requirements On-Receipt for QC Bench**	December 25, 2020	Dorna Zareianjahromi
• Removed QC using GC ATCC isolate with GC agar	Jan 8, 2021	Dorna Zareianjahromi
• Addition of Quantitative GMP Media Quality Control Chart and 50CFU/mL working suspension	Feb 01,2021	Dorna Zareianjahromi
• Addition of passage examples in Working stock section	Feb 10, 2021	Dorna Zareianjahromi

Page Number / Item	Date of Revision	Edited by:
• Addition of pa9027, sa6538, bs6633 , cs19404 and sub weekly from slant for ca10231 to the schedule for subculture of stuck cultures		
• Updated VISA isolation agar QC org	March 02, 2021	Wayne Chiu
• Revised GMP media QC sections	March 23, 2021	Wayne Chiu
Minor formatting change	April 11, 2021	Jessica Bourke
Nomenclature update – remove Clostridium difficle	April 19, 2021	Wayne Chiu
Added IMA to Appendix X	April 23, 2021	Wayne Chiu
Reformatted Appendix X	May 19, 2021	Wayne Chiu
Moved THIO, TSB, TSAwlec to GMP annual Added doxy KB to weekly QC list Updated GMP suspension prep procedure	June 10, 2021	Wayne Chiu
Updated etest qc for pseudo and ecoli	Aug 31, 2021	Wayne Chiu
Removed novobiocin from weekly qc, removed S sapro from weekly subculture list	Nov 2, 2021	Wayne Chiu
Updated appendix X – media requirements on receipt	Dec 14, 2021	Wayne Chiu
Updated manual to reflect the use of SoftTotal QC and how to navigate the software for all QC bench procedures	May 3, 2022	Melinda Kantor
Added Candida plus agar QC	May 12, 2022	Wayne Chiu
Added Aminopeptidase (bactident)	July 13, 2022	Wayne Chiu
Included instructions on cancelling order in TQC	July 21, 2022	Wayne Chiu
In “CULTURE MEDIA QUALITY CONTRO” section, changed the QC frequency of GMP media from annual to QC upon each new lot/shipment for the following: Thioglycolate Broth Tryptone Soya Broth Tryptic Soya Agar Lec/Tween55 Tryptic Soya Agar Lec/Tween	January 27, 2027	Oliver Li