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Prepared by QA Committee		
Issued by: Laboratory Manager	Revision Date: 8/9/2024	
Approved by Laboratory Director: Microbiologist-in-Chief	Next Review Date: 6/9/2026	

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Record of Edited Revisions

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Page Number / Item	Date of Revision	Signature of Approval
Annual Review	May 12, 2003	Dr. T. Mazzulli
Molecular Testing – HBV DNA-Reporting Added Para.	October 10, 2003	Dr. T. Mazzulli
AxSym System-Reporting Results HbsAg	October 28, 2003	Dr. T. Mazzulli
AxSym – CMV IgG Antibody (x)	October 28, 2003	Dr. T. Mazzulli
AxSym – Quality Control External Controls	October 28, 2003	Dr. T. Mazzulli
AxSym – Added Failed QC	October 28, 2003	Dr. T. Mazzulli
AxSym HbsAg Surface Antigen – Pt. Samples	January 22, 2004	Dr. T. Mazzulli
Appendix V (f) Added Steps	January 15, 2004	Dr. T. Mazzulli
HCV-RNA PCR Reporting – Positives	April 02, 2004	Dr. T. Mazzulli
Annual Review	May 26, 2004	Dr. T. Mazzulli
Page 6 – Interpretation of Results – OD changed for Positive and Indeterminate.	May 20, 2005	Dr. T. Mazzulli
Page 6, 15 – Run external control – include QC and instrument problems	May 20, 2005	Dr. T. Mazzulli
Page 8 – re-centrifuge cloudy, previously frozen, reconstituted samples.	May 20, 2005	Dr. T. Mazzulli
Page 8 – Refer to Abbott Operation Manual vol. 1&2 for specific maintenance procedures	May 20, 2005	Dr. T. Mazzulli
Page 13, 14 – report to MOH added	May 20, 2005	Dr. T. Mazzulli
Page 13, 14 – centrifuge before repeating	May 20, 2005	Dr. T. Mazzulli
Page 16, file log and external control out of range	May 20, 2005	Dr. T. Mazzulli
Page 48 – store VDRL samples for 3 months after testing	May 20, 2005	Dr. T. Mazzulli
Page 51 – 56 VZV Vidas revised	May 20, 2005	Dr. T. Mazzulli
Page 57 – WNV IgG not currently in use	May 20, 2005	Dr. T. Mazzulli
Page 61 – WNV IgM not currently in use	May 20, 2005	Dr. T. Mazzulli
Page 67 – Molecular Testing – <i>Chlamydia Trachomatis</i> & <i>Neisseria gonorrhoeae</i>	May 20, 2005	Dr. T. Mazzulli
Page 67 – urine but not more than 60 mL added	May 20, 2005	Dr. T. Mazzulli
Page 68 – specimen not lysed...added	May 20, 2005	Dr. T. Mazzulli
Page 68 – tubes may be blotted	May 20, 2005	Dr. T. Mazzulli
Page 70 – handling samples after lysing	May 20, 2005	Dr. T. Mazzulli
Page 71,72 Procedure change	May 20, 2005	Dr. T. Mazzulli

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Page 72, interpretation of result - change MOTA score	May 20, 2005	Dr. T. Mazzulli
Page 73, reporting – indeterminate	May 20, 2005	Dr. T. Mazzulli
Page 76 – do not vortex working master mix	May 20, 2005	Dr. T. Mazzulli
Page 76 – specimen dilution protocol	May 20, 2005	Dr. T. Mazzulli
Page 77 – 80 procedure and reporting changed	May 20, 2005	Dr. T. Mazzulli
Page 81 – QC procedure changed	May 20, 2005	Dr. T. Mazzulli
Page 93 – procedure changed	May 20, 2005	Dr. T. Mazzulli
Page 86 – 88, instrument instructions	May 20, 2005	Dr. T. Mazzulli
Page 90 – WNV RT-PCR	May 20, 2005	Dr. T. Mazzulli
Page 92 – lysis buffer	May 20, 2005	Dr. T. Mazzulli
Page 93 – General Precaution section revised	May 20, 2005	Dr. T. Mazzulli
Page 94-100 – procedure revised	May 20, 2005	Dr. T. Mazzulli
Page 101 – schedule revised	May 20, 2005	Dr. T. Mazzulli
Page 105 – shipping to St. Joseph’s	May 20, 2005	Dr. T. Mazzulli
Page 121 – shipping to HSC	May 20, 2005	Dr. T. Mazzulli
Annual Review	May 20, 2005	Dr. T. Mazzulli
Page 128 – Updated decontamination procedure	June 2, 2005	Dr. T. Mazzulli
Page 6 – C. difficile toxin indeterminate range changed	December 29, 2005	Dr. T. Mazzulli
Page 13 – HBc IgM reporting guide changed	December 29, 2005	Dr. T. Mazzulli
Page 15 – MV, Rubella reporting	May 29, 2006	Dr. T. Mazzulli
Annual Review	May 29, 2006	Dr. T. Mazzulli
Added links to TGLN Procedures	March 21, 2007	Dr. T. Mazzulli
Annual Review	June 8, 2007	Dr. T. Mazzulli
Added Labour and Delivery STAT HbsAg and HIV Instruction	March 19, 2008	Dr. T. Mazzulli
Added Immuncor Capture-CMV Assay	July 14, 2008	Dr. T. Mazzulli
Revised Document numbers	July 14, 2008	Dr. T. Mazzulli
Added Ortho ELISA Assays for Hbcore, HCV, HTLV I/II for Donor Testing	July 14, 2008	Dr. T. Mazzulli
Annual Review	July 14, 2008	Dr. T. Mazzulli
Report positive C. difficile toxin as an ISOLATE in the LIS	September 16, 2008	Dr. T. Mazzulli
Serology Referred Out Test Results Entry Phrases added	March 09, 2009	Dr. T. Mazzulli
Replaced HbsAg, HIV ½ HbcAb, HCV Ab, HTLV I/II Ab donor serology sections	November 18, 2009	Dr. T. Mazzulli
Added <i>Aspergillus</i> Galactomannan Antigen Detection	November 18, 2009	Dr. T. Mazzulli

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Assay		
Annual Review	November 18, 2009	Dr. T. Mazzulli
Architect System added	May 17, 2010	Dr. T. Mazzulli
<i>C. difficile</i> Toxin EIA edited with Premier kit	May 17, 2010	Dr. T. Mazzulli
Annual Review	May 17, 2010	Dr. T. Mazzulli
Remove <i>C. difficile</i> toxin EIA	January 10, 2011	Dr. T. Mazzulli
Syphillis screen added to Architect System	January 31, 2011	Dr. T. Mazzulli
Modified RPR for Cadaver donors	January 31, 2011	Dr. T. Mazzulli
Updated AxSYM procedure	January 31, 2011	Dr. T. Mazzulli
Updated VZV procedure	January 31, 2011	Dr. T. Mazzulli
Updated Appendix II	January 31, 2011	Dr. T. Mazzulli
Updated Architect procedure	May 31, 2011	Dr. T. Mazzulli
Removed Appendix III – Send out procedure to St. Joseph Hospital, Hamilton ON	May 31, 2011	Dr. T. Mazzulli
Replaced Appendix III – Daily work-up for Architect Bench	May 31, 2011	Dr. T. Mazzulli
Moved PCP DFA from Virology Section	May 31, 2011	Dr. T. Mazzulli
Annual Review	May 31, 2011	Dr. T. Mazzulli
Architect system – added HTLV	June 20, 2011	Dr. T. Mazzulli
Removed HTLV for TGLN	June 20, 2011	Dr. T. Mazzulli
Added to Table of Contents Donor Serology and Molecular Testing at Mount Sinai Hospital for TGLN	July 15, 2011	Dr. T. Mazzulli
Architect system – added CMV IgM and CMV avidity	March 20, 2012	Dr. T. Mazzulli
Annual Review	March 20, 2012	Dr. T. Mazzulli
Edited CMV Avidity testing procedure	September 12, 2012	Dr. T. Mazzulli
Added Appendix XI and XII – CMV Avidity workflow	September 12, 2012	Dr. T. Mazzulli
Edited Architect system	September 30, 2012	Dr. T. Mazzulli
Edited EBV serology	September 30, 2012	Dr. T. Mazzulli
Edited Autoverification procedure	September 30, 2012	Dr. T. Mazzulli
Removed AxSYM HhsAg confirmation	September 30, 2012	Dr. T. Mazzulli
Edited Immucor CMV procedure	September 30, 2012	Dr. T. Mazzulli
Updated Cadaver serology procedure	September 30, 2012	Dr. T. Mazzulli
Edited Syphilis Screen RPR Serology procedure	September 30, 2012	Dr. T. Mazzulli
Updated Architect daily workflow	September 30, 2012	Dr. T. Mazzulli
Added George Washington CMV avidity confirmation	January 28, 2013	Dr. T. Mazzulli

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algorithm		
Updated Appendix IV – Entering and Verifying Refer-out Serology Results	February 12, 2013	Dr. T. Mazzulli
Updated EBV Serology, reference added	February 28, 2013	Dr. T. Mazzulli
Annual Review	April 18, 2013	Dr. T. Mazzulli
Edited George Washington CMV avidity confirmation algorithm	April 18, 2013	Dr. T. Mazzulli
Added George Washington Anti-HCV algorithm	April 18, 2013	Dr. T. Mazzulli
Updated TGLN Call Back procedure	May 21, 2013	Dr. T. Mazzulli
Updated Architect section	May 31, 2013	Dr. T. Mazzulli
Updated Appendix IV – refer-out tests reporting	May 31, 2013	Dr. T. Mazzulli
Update Architect, Axsym, DONOR, Immucor, appdx3, appdx 5	September 17, 2013	Dr. T. Mazzulli
Addition Appendix XII, modify appendix I and III, delete appendix VII	October 30, 2013	Dr. T. Mazzulli
Edit Appendix XII, include chemical waste transport.	January 15, 2014	Dr. T. Mazzulli
Moved GW in its own section. Add reporting/ receiving section. Update Appendix XII include easy mag transport	January 27, 2014	Dr. T. Mazzulli
EBV VCA IgG/EBV EBNA-1 IgG addition to architect manual.	March 11, 2014	Dr. T. Mazzulli
GW HC flowchart update, GW confirm algorithm update	March 14, 2014	Dr. T. Mazzulli
GW HCV flowchart update, Appendix update, Axsym manual update – remove CMV	March 27, 2014	Dr. T. Mazzulli
Appendix III update	April 4, 2014	Dr. T. Mazzulli
Removal of Axsym manual. Addition of Donor section to Architect Manual. Note addition to STAT needlestick incident reporting	May 28, 2014	Dr. T. Mazzulli
Annual review		
Remove Evolis donor manual, replace with Gw hcae evolis manual	October 24, 2014	Dr. T. Mazzulli
Update Architect manual.		
Removal of Evolis donor testing		
Fix headers/footers		
Indeterminate CMV Immucor interpretation added.	May 1, 2015	Dr. T. Mazzulli
TGLN section removed and copied to standalone TGLN call back procedure. Link to this manual created.		
GW procedure: CMV Avidity Troubleshooting added:	May 1, 2015	Dr. T. Mazzulli

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diluting sample when CMV IgG is too high to calculate avidity Donor testing RPR to 8VD		
-Wash buffer filling replaced with ARM procedure. -Added under Donor/Recipient Serology reporting: Reporting REACTIVE results for <u>Alberta Donors</u> only: - If repeat results support the initial Reactive result, enter repeat results in the result comment and verify results. – If repeat results DO NOT support the initial result, type “Note” at result area, enter initial result and repeat results in the comment and verify results. -Donor/Recipient resulting divided into Ontario living donor and non-ontario & cadaveric donor sections	June 17, 2015	Dr. T. Mazzulli
Hep C Ab, HIV , HTLV and VD for living donor: Repeatedly positive report as ‘reactive’ with comment “Repeatedly reactive, sent to PHL for further testing”	August 7, 2015	Dr. T. Mazzulli
Annual Review Remove 8HAG (replace with 8HAGX) Remove 8HBEB, 8HBEG tests Update 8HAGX positive reflex procedure/resulting table Removed flowcharts for 8HAGX algorithm Update 8HAGX confirmation interpretation table Added description of reagents used in Working Wash solution for CMV Immucor. Remove Alberta Only reporting for Donors Add donor storage instructions Updated Donor reporting table	October 15, 2015	Dr. T. Mazzulli
p.3 Immucor CMV for wash solution added phrase: ‘Mark ‘ Date Made’ on Working Wash Solution bottle.’ p.4 Immucor CMV: step 8: changed from wash gently 5 times to gently 6 times. p.4 Immucor CMV: Interpretation of results for Donors removed: ‘Donor samples received from the architect bench (8HAGX) for Capture-CMV testing must be resulted and verified under both 8CMSE and 8CMS’ p.4 Step 11 inserted RCF specific to ImmuSpin centrifuge programming.	October 29, 2015	Dr. T. Mazzulli

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p.5 Immucor CMV: QC changed external controls from Run Virotrol I/ViroTorch to ViroTorch/ ViroTorch-M. p.5 Immucor CMV: Reference updated with version: Insert code 325-13 Rev 9/10		
Added Routine Patient HbsAgQ2 Auto Testing Algorithm Expanded Interpretation of HsbAg Qualitative II Confirmatory Results	November 2, 2015	Dr. T. Mazzulli
Reflex testing chart - added link to confirmation page - Removed yellow highlighting from HBC reflexing	December 9, 2015	Dr. T. Mazzulli
Reflex/resulting table called "8HCA" from "HCA" (p.18) -Added EBV reflex table for routine patients	February 9, 2016	Dr. T. Mazzulli
Document archived and separted into invidiual manuals. Removed Shipment of samples to HSC – archived. No longer done. Transferred Entering of referred out results appendix to Refer out results procedure QPCMI17001 .	May 17, 2016	Dr. T. Mazzulli
Annual Review	October 15, 2016	Dr. T. Mazzulli
Moved GAL worksheet under GAL manual. Added link to serology external control selection criteria	February 16, 2017	Dr. T. Mazzulli
Annual Review Syphilis RPR test retired (removed)	August 11, 2017	Dr. T. Mazzulli
Addition of Galactomannan repeat form.	February 19, 2018	Dr. T. Mazzulli
Annual Review	October 15, 2019	Dr. T. Mazzulli
Annual Review	October 15, 2020	Dr. T. Mazzulli

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

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Minor formatted changes	April 11, 2021	Jessica Bourke
Added Alinity Manual	Nov 18, 2021	Wayne Chiu
Removed George Washington study	Dec 1, 2021	Wayne Chiu
Removed PJP DFA	Dec 15, 2021	Jessica Bourke
Removed Architect link	September 22, 2022	Jessica Bourke
Added VIDAS CMVM link	April 05, 2022	Qin Liu
Minor formatting change	August 09, 2024	Oliver Li

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