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| Prepared by QA Committee | | |
| Issued by: Laboratory Manager | Revision Date: 2/28/2023 | |
| Approved by Laboratory Director: Microbiologist-in-Chief | Next Review Date: 2/28/2025 | |

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[Cytomegalovirus Quantitative PCR by Cobas® Cobas 6800](#)

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[Enterovirus \(EV\) RNA detection in cerebrospinal fluid \(CSF\) by PCR Cepheid GeneXpert](#)

[Epstein Barr Virus Quantitative PCR Altona Bio-Rad CFX90](#)

[Hepatitis B, Hepatitis C, HIV Donor Screen NAT PCR by Cobas® 6800](#)

[Herpes Simplex Virus Varicella-Zoster PCR by Bio-Rad CFX96](#)

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[Parvovirus B19 Qualitative PCR Bio-Rad CFX96](#)

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[VRE vanA and vanB PCR by Cepheid GeneXpert](#)

[West Nile Virus NAT PCR by Cobas® 6800](#)

[SARS-CoV-2 Virus PCR by Luminex Aries](#)

[SARS-CoV-2 PCR by MGI](#)

[SARS-CoV-2 PCR by Allplex™ Seegene](#)

[SARS-CoV-2 PCR by Roche Cobas 6800](#)



[SARS-CoV-2 PCR by Cepheid GeneXpert](#)

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[SARS-CoV-2/Flu/RSV PCR by Cepheid GeneXpert](#)

[SARS-CoV-2 Resp Pathogen Panel NxTAG RT-PCR by Luminex](#)

[SARS-CoV 2 VOC procedure](#)

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Record of Edited Revisions

Manual Section Name: Molecular Diagnostic Tests



| Page Number / Item | Date of Revision | Signature of Approval |
|---|-------------------|-----------------------|
| Molecular Testing - HBV DNA-Reporting Added Para. | October 10, 2003 | Dr. T. Mazzulli |
| Annual Review | May 30, 2004 | Dr. T. Mazzulli |
| Page 67 - Molecular Testing - Chlamydia Trachomatis & Neisseria gonorrhoeae | 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 |
| 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 128 – Updated decontamination procedure | June 2, 2005 | Dr. T. Mazzulli |
| Annual Review | May 30, 2006 | Dr. T. Mazzulli |
| Added links to TGLN Procedures | March 21, 2007 | Dr. T. Mazzulli |
| Revised HBV-DNA and HCV-RNA procedures with Ampliprep instructions | May 11, 2008 | Dr. T. Mazzulli |
| Procleix Ultrio and WNV added | July 21, 2008 | Dr. T. Mazzulli |
| Procleix Discriminatory Assay | July 21, 2008 | Dr. T. Mazzulli |
| Annual Review | July 21, 2008 | Dr. T. Mazzulli |
| CMV DNA Amplification and Detection Procedures updated | November 01, 2008 | Dr. T. Mazzulli |
| Molecular Testing – updated | November 01, 2008 | Dr. T. Mazzulli |

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|---|--------------------|-----------------------|
| EBV DNA Amplification and Detection Procedures updated | November 01, 2008 | Dr. T. Mazzulli |
| HSV DNA Amplification and Detection Procedures updated | November 01, 2008 | Dr. T. Mazzulli |
| Parvovirus B19 DNA PCR Amplification and Detection Procedures updated | November 01, 2008 | Dr. T. Mazzulli |
| Enterovirus RNA Amplification and Detection Procdeures added | November 01, 2008 | Dr. T. Mazzulli |
| West Nile Virus RT PCR - Failed QC added | July 10, 2009 | Dr. T. Mazzulli |
| Annual Review | July 31, 2009 | Dr. T. Mazzulli |
| Annual Review | July 31, 2010 | Dr. T. Mazzulli |
| Added revised easyMag | August 23, 2010 | Dr. T. Mazzulli |
| Added revised CMV PCR | August 23, 2010 | Dr. T. Mazzulli |
| Added revised BKV PCR | October 31, 2010 | Dr. T. Mazzulli |
| GeneXpert C. difficile added | January 10, 2011 | Dr. T. Mazzulli |
| Updated Procleix Ultrio | April 14, 2011 | Dr. T. Mazzulli |
| Updated QC section of easyMag extraction | May 31, 2011 | Dr. T. Mazzulli |
| Updated Influenza procedure | May 31, 2011 | Dr. T. Mazzulli |
| Added Virology specimen accessioning guide link | May 31, 2011 | Dr. T. Mazzulli |
| Deleted CMV DNA Amplification and Detection Procedures by Lightcycler | May 31, 2011 | Dr. T. Mazzulli |
| Deleted VZV Amplification and Detection Procedures by Lightcycler | May 31, 2011 | Dr. T. Mazzulli |
| Deleted HSV Amplification and Detection Procedures by Lightcycler | May 31, 2011 | Dr. T. Mazzulli |
| Added HSV/VZV Detection (Altona Alpha herpes) | May 31, 2011 | Dr. T. Mazzulli |
| Added Multiplex Respiratory virus detection | May 31, 2011 | Dr. T. Mazzulli |
| Annual Review | May 31, 2011 | Dr. T. Mazzulli |
| Parvovirus PCR revised | May 31, 2011 | Dr. T. Mazzulli |
| RSV PCR added | May 31, 2011 | Dr. T. Mazzulli |
| Replace Procleix with MPX | September 11, 2011 | Dr. T. Mazzulli |
| Updated WNV PCR with Altona kits | June 13, 2012 | Dr. T. Mazzulli |
| Annual Review | June 13, 2012 | Dr. T. Mazzulli |
| Added Appendix VIII - epMotion procedure | June 13, 2012 | Dr. T. Mazzulli |
| Added Appendix VII - Creating Standard Curve for Quantitative PCRs | June 13, 2012 | Dr. T. Mazzulli |

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| Page Number / Item | Date of Revision | Signature of Approval |
|---|--------------------|-----------------------|
| Added Links to RotorGene Worksheets and calculations and reports | June 13, 2012 | Dr. T. Mazzulli |
| Chlamydia/Neisseria gonorrhoeae detection method changed to Roche COBAS 4800 | October 17, 2012 | Dr. T. Mazzulli |
| Appendix II to IV BD ProbeTec related documents removed | October 17, 2012 | Dr. T. Mazzulli |
| Added HPV testing | December 12, 2012 | Dr. T. Mazzulli |
| Added Focus Simplexa Flu A/B and RSV testing | December 12, 2012 | Dr. T. Mazzulli |
| Moved RotorGene Flu and RSV tests to Appendix II and III for backup use | December 12, 2012 | Dr. T. Mazzulli |
| Renumbered procedures | December 12, 2012 | Dr. T. Mazzulli |
| Revised Positive C. diff resulting message | February 05, 2013 | Dr. T. Mazzulli |
| Expanded C. diff resulting messages | April 18, 2013 | Dr. T. Mazzulli |
| Realigned bullets and numbering format | July 31, 2013 | Dr. T. Mazzulli |
| Added Appendix XI WNV PCR Procedure abbreviated | July 31, 2013 | Dr. T. Mazzulli |
| Update QC & Maintenance for Focus Simplexa Flu A/B and RSV testing | July 31, 2013 | Dr. T. Mazzulli |
| Annual Review | July 31, 2013 | Dr. T. Mazzulli |
| MPX procedure updates | December 9th, 2013 | Dr. T. Mazzulli |
| Simplexa Flu A/B and RSV reporting procedure updated | December 18, 2013 | Dr. T. Mazzulli |
| Simplexa Flu A/B and RSV testing procedure updated | January 15, 2014 | Dr. T. Mazzulli |
| Addition of Appendix IV: Simplexa A/B/RSV worksheet | January 24, 2014 | Dr. T. Mazzulli |
| Manual Creation: Cobas Ampliprep/TaqMan CMV PCR MI/MD/19/v01 | February 21, 2014 | Dr. T. Mazzulli |
| Reporting C.diff GeneExpert Updating | April 14, 2014 | Dr. T. Mazzulli |
| C.diff reporting update, WNV PCR manual and WNV PCR abbreviated appendix dry spin time update. Annual Review | May 28, 2014 | Dr. T. Mazzulli |
| Removed Luminex, HBV DNA, HCV RNA procedure Updated MPX NAT to new version and in its own manual as well as WNV NAT Updated Virology accessioning chart to its own manual Move Easymag manuals to Appendix Updated APPENDIX I - Molecular Diagnostic Tests Schedule | November 3, 2014 | Dr. T. Mazzulli |
| C. diff reporting update for results | November 12, 2014 | Dr. T. Mazzulli |

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| Addition of : Sputolysin Procedure and Stool preparation in Virology Accessioning tables split and updated Simplexa manual resulting updated. | January 28, 2015 | Dr. T. Mazzulli |
| Parainfluenza and human Metapneumovirus procedure added | February 18, 2015 | Dr. T. Mazzulli |
| Update C.diff comments | February 26, 2015 | Dr. T. Mazzulli |
| Parainfluenza and human Metapneumovirus BIORAD procedure added | March 15, 2015 | |
| Added C. diff with eSwab section | May 6, 2015 | Dr. T. Mazzulli |
| Added links for BK/EBV to calculation excel worksheet | May 6, 2015 | Dr. T. Mazzulli |
| p.8 BK general precautions modified | May 6, 2015 | Dr. T. Mazzulli |
| Added introduction and specimen collection/transport to BKV section and updated materials section | May 6, 2015 | Dr. T. Mazzulli |
| Adenovirus PCR by Rotorgene Section Added in | May 6, 2015 | Dr. T. Mazzulli |
| Added: ROTORGENE QC Semi-Annual: Perform optical temperature verification | June 15, 2015 | Dr. T. Mazzulli |
| Annual Review Added Appendix XI – Rotorgene Optical Temperature Verification (OTV) Procedure Added link in WNV PCR to OTV Procedure Added PCR ordering chart to accessioning section | June 15, 2015 | Dr. T. Mazzulli |
| Updated BK Virus procedure | June 25, 2015 | Dr. T. Mazzulli |
| Updated BK Manual section, Updated full EBV manual BK and EBV manual addition of summary information | July 16, 2015 | Dr. T. Mazzulli |
| South West Health Ordering information added to PCR accessing chart. | August 12, 2015 | Dr. T. Mazzulli |
| Virology specimen accessioning guide changes: -add tx pt to edta for hz, -add pleural to peritoneal/pericardial fluids (entero) -removed “if requested” Entero from BALs -removed adeno to PHL from eye specimens (done in house) | September 1, 2015 | Dr. T. Mazzulli |
| Herpes simplex Virus Varicella-Zoster Virus PCR by | September 3, 2015 | Dr. T. Mazzulli |

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| Bio-Rad CFX96c added manual | | |
| Influenza Simplexa section: - added report using virology worklist Respiratory PCR - Error EC500 retest 1:10 - Add media PRABR if retesting simplexa sample - Add dates in media PCABR WNV Rotorgene: - Removed use of 72-well rotor parts - Document which rotorgene was used (blue or red) - Removed Red Channel RSV A (typo) p.172 - Reporting section: note for positives to re-extract from original clot and re run, for donors repeat in duplicates & record CT values in PCWNV media. | September 11, 2015 | Dr. T. Mazzulli |
| -Updated troubleshooting section Influenza Simplexa manual & added instructions for insufficient sample error. -Reorganize manuals alphabetically | September 25, 2015 | Dr. T. Mazzulli |
| Under trouble shooting section of manuals: MPX NAT, WNV NAT, Chlamydia PCR added to the table if IC fails: First time: repeat Second time: result as invalid with result comment @SPIN “Likely due to specimen integrity, unable to obtain valid test result after repeated attempts.” Added BK BIO RAD section | October 7, 2015 | Dr. T. Mazzulli |
| Virology Accessioning Chart changes: Adeno request for stool send to PHL, parvo request on plasma: requires microbiologist approval | October 15, 2015 | Dr. T. Mazzulli |
| Under Virology ordering chart added link to Send out Manual for processing specimens to be send for external testing. | October 20, 2015 | Dr. T. Mazzulli |
| Updated MPX NAT and WNV NAT to include storage temperature of reagents Updated WNV storage conditions of specimen | October 26, 2015 | Dr. T. Mazzulli |
| Added to PCR order entry chart: | October 30, 2015 | Dr. T. Mazzulli |

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| River Valley Health (Part of Horizon Health Network) Update Reporting positive for WNV NAT | | |
| Manual sections converted into separte individual documents. Links provided here in TOC format. Remove/Archived sections: -WNV PCR by Rotorgene -Flu & RSV by Rotorgene appendix | December 2, 2015 | Dr. T. Mazzulli |
| Mycobacterium tuberculosis & Rifampicin resistance PCR by Cepheid GeneXpert Added Virology worksheets Added Respiratory Panel Luminex manual added VRE Cepheid Added | February 10, 2015 | Dr. T. Mazzulli |
| Annual Review | June 15, 2016 | Dr. T. Mazzulli |
| Added Aries Manual Influenza | August 16, 2016 | Dr. T. Mazzulli |
| Archived:: BK Virus Quantitative PCR By Rotorgene Adenovirus Qualitative RTPCR by Rotorgene Added: Adenovirus Qualitative PCR Bio-Rad CFX96 | August 24, 2016 | Dr. T. Mazzulli |
| Epstein Barr Virus Quantitative PCR by Rotorgene Updated UHN/MSH logo | August 25, 2016 | Dr. T. Mazzulli |
| Archived Cytomegalovirus Qualitative PCR by Rotorgene Inserted CMV Quantitative PCR by BIORAX CFX96 Added Parvovirus B19 Qualitative PCR Bio-Rad CFX96 Removed HZ Rotorogene PCR manual | August 30, 2016 | Dr. T. Mazzulli |
| Removed Simplexa manual - no longer in use. Influenza AB & RSV PCR by Focus Diagnostics Simplexa™ CRE PCR link added | September 7, 2016 | Dr. T. Mazzulli |
| Annual Review Removed Enterovirus by Light Cycler and replaced with Enterovirus CSF by Cepheid Procedure. | April 6, 2017 | Dr. T. Mazzulli |
| Addition of Cytomegalovirus Quantitative PCR by Cobas® 6800 | May 29, 2017 | Dr. T. Mazzulli |
| Clostridium difficile PCR by Luminex ARIES® | September 30, 2017 | Dr. T. Mazzulli |
| Added VRE Roche PCR by Lightcycler | December 18, 2017 | Dr. T. Mazzulli |
| Added HZ by Lumined Aries | February 1, 2018 | Dr. T. Mazzulli |

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| Addition of WNV and Hepatitis B, C, HIV NAT PCR by Cobas 6800 documents to table of contents. | February 5, 2018 | Dr. T. Mazzulli |
| Archival of Hepatitis B, Hepatitis C, HIV Donor Screen NAT PCR by Hepatitis B, Hepatitis C, HIV Donor Screen NAT PCR by Cobas® s201 Ampliprep TaqMan & WNV by Cobas s201 Ampliprep TaqMan | February 19, 2018 | Dr. T. Mazzulli |
| Archived CMV Quantitative by Ampliprep/TaqMan | March 6, 2018 | Dr. T. Mazzulli |
| Annual Review Added Encephalitis (ME) Biofire manual | April 13, 2018 | Dr. T. Mazzulli |
| Addition of Qualification for CFX96 Deep Well™ Real-Time System | June 15, 2018 | Dr. T. Mazzulli |
| Addition of Pneumocystis jirovecii (PJP) Quantitative PCR Bio-Rad CFX96 manual | December 5, 2018 | Dr. T. Mazzulli |
| Annual Review EBV and BK Altona manuals added | January 20, 2019 | Dr. T. Mazzulli |
| Updated CTNG manual to 6800 procedures | December 13, 2019 | Dr. T. Mazzulli |
| Annual Review Removal of VRE by Light Cycler Removed epimotion manual Addition of SARS-CoV-2 Manual | March 15, 2020 | Dr. T. Mazzulli |
| Addition of SARS-CoV-2 Virus PCR by Luminex Aries SARS-CoV-2 PCR by Altona RealStar | May 15, 2020 | Dr. T. Mazzulli |

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



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| Addition of SARS-CoV-2 PCR by MGI and Roche Cobas 6800 procedures | June 16, 2021 | Jessica Bourke |
| Addition of SARS RPP by luminex, removed RPP by luminex | Jan 8, 2021 | Jessica Bourke |
| Addition of SARS VOC by MGI procedure | Feb 22, 2021 | Oliver Li |
| Updated SARS VOC to include E484K gene procedure | April 12, 2021 | Jessica Bourke |
| Added Cepheid genexpert for covid | Nov 9, 2021 | Wayne Chiu |
| Added Abbott ID now for covid | Dec 24, 2021 | Wayne Chiu |
| Added CTNG genexpert | Feb 1, 2021 | Wayne Chiu |
| Added monkeypox procedure | May 27, 2022 | Wayne Chiu |
| Removed monkeypox procedure. Moved to individual | June 14, 2022 | Jessica Bourke |

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| Safety main protocol. | | |
| Removed SARScov by Altona link | June 28, 2022 | Wayne Chiu |
| Remove HPV by Cobas 4800 Addition of HPV by Cobas 6800 | October 9, 2022 | Jessica Bourke |
| Renamed link for Clostridium difficile to C difficile | Nov 17, 2022 | Wayne Chiu |
| Fixed hyperlinks for C difficile documents | Feb 2, 2023 | Wayne Chiu |
| Removed IDnow hyperlink, test discontinued | Feb 28, 2023 | Wayne Chiu |
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