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Approved by Laboratory Director: Microbiologist-in-Chief	Annual Review Date: 11/1/2019	

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[Epstein Barr Virus Quantitative PCR Bio-Rad CFX96](#)

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

[Herpes Simplex Virus Varicella-Zoster PCR by Luminex ARIES®](#)

[Human Papilloma Virus \(HPV\) by Cobas 4800](#)

[Influenza A, B & RSV PCR by Luminex ARIES](#)

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

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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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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
Added Encephalitis (ME) Biofire manual	April 13, 2018	Dr. T. Mazzulli
Addition of Qualification for CFX96 Deep Well TM 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

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