**University of Washington Medical Center**

Clinical Microbiology Laboratory Document #616.U.201.09

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| Serology Manual  **Serology Testing and Review Information** | | Effective: |
| Written by: Ro Bacina | Reviewed by: Sarah Jensen | Approved by: Andrew Bryan |
| Revises or supersedes: Serology Specimens 8/1/14, Serology Reagent and Test Information 11/21/17, Policy Regarding the Use of Outdated Kit Components 7/24/11, Policy for Detecting Clerical Errors, Verifying and Correcting Results in Serology 5/15/12 | | Revised by: Jennifer Vong |

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| ANNUAL REVIEW | | | |
| Reviewed by: | Date | Reviewed by: | Date |
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**I. Available Tests and Frequency of testing**

A. Please refer to the Online Test Guide for up to date information regard test frequency.

B. Available tests in serology are: ASO, Aspergillus Galactomannan, Biofire GI, Cryptococcal antigen, Giardia antigen, Cepheid Xpert *C. difficile* toxin assay, Cepheid Xpert Flu/RSV Rapid PCR assay, *Legionella* urine antigen, *Streptococcus pneumoniae* urine antigen

**II. Kit and Reagent Information**

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| Description | Mfg./Vendor | Proficiency Testing |
| Crytococcal Antigen Lateral Flow Assay | Immuno-Mycologics | CAP |
| ASO SeraTest | UWMM Remel BL | CAP |
| Strep Pneumo Kit, Binax Now | Alere | CAP |
| Urine Legionella Antigen, Binax Now | Alere | CAP |
| Prospect Giardia Microplate Assay | Remel | CAP |
| Aspergillus Galactomannan | Bio-Rad | CAP |
| Xpert C.difficile | Cepheid | CAP |
| Xpert Flu/RSV Xpress | Cepheid | CAP |

Note: Components of commercial kits should only be used within the same kit lot number. Different lot numbers should not be interchanged.

**III. Outdated Materials**

1. All reagent kits and individual reagents used for patient testing must be used prior to expiration date. The use of outdated or expired reagents for patient testing is NOT allowed.
2. Outdated reagents may be used for research and development or for training purposes ONLY.
3. Kits and reagents for research, development and training must be clearly marked as “Research Only” or “Training Only”.

**IV. Serology Results and QC Review**

1. Reviewing Serology Tests

To help avoid transcription errors, completed daily completed worksheets should be printed. The Serology Lead Tech or MLS II will use this in comparison with the previous day’s handwritten worksheets/reports to check for transcription errors and to ensure other test requirements were followed. The Cepheid instrument is interfaced with the LIS, checking the completed worksheet against the handwritten worksheet is unnecessary.

1. Amended Report

If the serologist discovers that an erroneous result has been filed in the computer or given verbally, an amended report should be filed in the computer as soon as possible. The licensed care provider or outside lab should be called immediately. A Microbiology QA Form should be filled out and submitted.

1. Overdue Test Log

The serologist should look at the overdue test log weekly to see what tests are still pending in the serology section. If results have been finished but not finalized in the computer, then these results should be entered as soon as possible. If, for some reason, a test was not run or a specimen not received, the specimen should be located and the test performed or the reason the specimen has not arrived should be determined (e.g. QNS, patient refused draw, specimen broken, etc). Credits should be issued as appropriate and a report generated stating that the test has been credited and the reason.

1. Quality Control
2. Results of controls for each test are recorded on appropriate sheets in serology QC Book. Defined tolerance limits are included on Q.C. sheets. QC data will be reviewed weekly by the serology lead tech or MLS II.
3. Levy Jennings charts for Aspergillus galactomannan are reviewed monthly (lead technologist in charge of section, or designee) for shifts and trends. If there is a significant change in statistics from previous data, the following action protocol is initiated:
   1. Attempts will be made to establish possible cause of such change
4. Data will be reviewed for extreme outliers, which should have been excluded from data calculations.
5. Data will be reviewed for shifts and trends over the whole of the period being calculated.
6. Causes of shifts and/or trends will be investigated and corrective action will be taken as appropriate.

b. When appropriate, control mean will be recalculated and a new range will be established based upon the most current data.

**V. Revision Record**

A. 3/30/11: All references to RPR and VDRL have been removed. These tests are no longer done in Serology.

3/30/11: *C. difficile* antigen detection has been replaced with Toxogenic *C. difficile* nucleic acid amplification

3/30/11: Aspergillus Galactomannan is performed Monday, Wednesday, and Friday.

1. 5/15/12: All references to Fungal Immunodiffusion have been removed.

5/15/12: All references to N. gonorrhoeae and Chlamydia nucleic acid amplification detection performed by HMC have been removed.

5/15/12: Added Section V. Merged from previous document 616.U.202.04.

5/15/12: Section V, G., added section for stools from children <2 as unacceptable for toxigenic C. difficile testing. Stools from previous positive patient received within 10 days and duplicate samples sent within a 24 hour period will be rejected.

1. 9/10/13: Changed the days of the week that Giardia antigen testing is performed to reflect current practice.
2. 4/28/14: Added Strep pneumoniae urine antigen reporting frequency and rejection information

4/28/14: Removed section II: Specimen delivery.

E. 8/1/14: Section II: Added comment about acceptable specimen types

8/1/14: Section II, B, 1: Specimen types for ASO and Streptozyme added

8/1/14: Section II, B, 2: Specimen types for OSOM Strep A and *S. pneumoniae*  antigen

tests added

8/1/14: Section II, C: Heading changed to Stool toxin tests and Shiga toxin test added

8/1/14: Section III: Heading changed to Frequency of testing (previoused called

Reporting) and Shiga Toxin test added to section

8/1/14: Section IV,H: Shiga toxin test added in unacceptable specimen list

F. 3/15/18: Major revision: removed section I, II, and IV. Information regarding testing and specimen collection can be found in individual testing procedures. Revised section III to list current tests and frequency of testing. Changed title of document to ‘Serology Testing and Review Information’.

Added relevant information from the following procedures: Serology Reagent and Test Information (618.U.304.02) 11/21/17, Policy Regarding the Use of Outdated Kit Components (616.U.205.03) 7/24/11, Policy for Detecting Clerical Errors, Verifying and Correcting Results in Serology (616.U.204.04) 5/15/12. And retired them all.