PROVIDENCE
Sacred Heart
Medical Center &
Children's Hospital

Package Insert Verification Procedure

Department of Microbiology

Effective date: 08/05/2010

Last Revision: 12/19/2014

Last reviewed: 12/19/2014

1.0 Purpose

Most diagnostic test products contain package inserts supplied by the manufacturer. In some cases the package insert may not be supplied with the product but may be accessed and printed from the manufacturer's website. These package inserts contain technical information for specimen requirements, test procedure, result interpretation, quality control testing and test limitations. Manufacturers may periodically update package inserts. A revision may include technical information that is important to the user. Changes that may affect the performance of the test or interpretation of results must be identified prior to using the test for clinical analysis. Utilizing altered test products without noting changes by the manufacturer could affect test results and lead to adverse management of patient care. This protocol is intended to help identify changes in package inserts and, if necessary, update the appropriate Microbiology standard operating procedures.

2.0 Procedure

2.1 Products that Require Package Insert Verification

1. Routine Bacteriology
   - API 20 E & API Coryne
   - CarboFerm Neisseria Kit
   - Crystal Anaerobe ID Kit
   - E. coli O157 Latex Test Reagent Kit
   - FA Test Kits: *Legionella*, *Pneumocystis*, *Bordetella*
   - Immuno*Card* STAT! EHEC
   - Staphtex
   - Streptex A, B, and Enzyme
   - Wellcolex Salmonella & Shigella
2. Molecular
   - Affirm VP III
   - Cdiff PCR Kit
   - MRSA PCR Kit
   - GBS PCR Kit
   - Enteric Bacterial Panel PCR Kit
   - BioFire FilmArray Kits
3. Mycobacteriology
   - BACTEC MGIT 960 PZA Kit & SIRE Kit
4. Mycology
   - Cryptococcal Antigen Lateral Flow Assay
5. Virology
   - Determine HIV 1&2 Ag-Ab Combo
   - Acceava Mono II
   - Acceava Strep A

2.2 Verification Procedure

1. Prior to using any new lot of a test, compare the package insert with the insert from the previous lot. An insert from the current lot should always be available for comparison. These inserts are stored in binders with the procedure manuals in each respective area.
2. If the revision date on the new package insert is the same and there are no indications of revisions, document your review on the package insert tracking sheet by recording the current date, the lot number of the new kit, the insert revision date, and your initials.
3. If the product packaging contains a notice from the manufacturer that the insert has been revised or if the revision date of the new package insert is different from the previous package insert:
    - Review the new package insert for changes by comparing it to the previous package insert.
    - If the revisions to the product insert are related to test performance or result interpretation, do not use the new test product until a procedural review has been completed.
    - Record the lot number and new insert revision date on the tracking sheet.
    - Notify the technical specialist, supervisor, or technical director.
4. Once the procedural review has been completed, any procedural revisions must be posted for technical staff to review and sign off.
5. The technical specialist should keep all older versions of package inserts on file.

3.0 Document Control History

Microbiology Director Approval: Dr. Ann Robinson 08/05/2010

Microbiology Supervisor Reviews: Jerry Claridge 08/05/2010, 08/2011, 08/2012, 12/19/2014

Revisions: 06/25/2013 updated kits – deleted GenProbe and modified PCR assays. 01/14/2014 changed Staphaurex to Staphtex and added BioFire FilmArray kits. 05/12/2014 Changed Cryptococcus Antigen from Latex to Lateral Flow Assay. 12/19/2014 Added Enteric Bacterial Panel, modified HIV kit, deleted influenza and RSV.

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Package Insert & QC Tracking Log for New Lots

Reagent:

Date	Reagent Lot Number	Control Lot Number*	QC Pass/Fail	P.I. Revision Date	Initials

***Each new lot must be tested using the <u>same lot of QC material</u> used for the previous lot for performance comparison.**