PROCEDURE
Corewell Health East - Parallel Testing Using Kit Controls - Dearborn, Taylor, Trenton, Wayne

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Dearborn Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Chemistry

1. Principle
This document is intended to provide instructions for testing personnel to perform parallel testing for Quality Control (QC) and Reagent Verification for Group A Strep, Mono and C. diff test kits.
Clinical laboratory reagents and control materials are exposed to many variables due to conditions during transportation and storage environments in different laboratory settings. The validation of new shipments and/or new lot numbers of test kits with currently in use test kits is performed to ensure that, despite varying environmental conditions, there are no clinically significant differences in the results obtained when different shipments and/or new lot numbers of reagents are used. Control materials are parallel tested to verify that the same results are achieved using reagents from each test kit.

2. Responsibility
Personnel who have completed the competency requirements will perform this testing.

3. Specimen
A. Test kit controls, or
B. Previously positive and previously negative patient samples, or
C. Previously run positive and negative College of American Pathologist (CAP) survey samples.

4. Reagent/Equipment Needed
A. Acceava® Strep A kit
B. Sure-Vue™ Mono Test kit
C. C. DIFF Quik Check Complete® test kit

5. Procedure
A. See individual test procedures for testing information.
   1. Corewell Health East - Sure-Vue Mono Test - All Beaumont Hospitals
   2. Corewell Health East - Strep Screen, Group A - All Beaumont Hospitals
   3. Corewell Health East - C. difficile GDH / Toxin - All Beaumont Hospitals

B. Each new shipment and/or new lot number of test kits are tested in parallel with the “kit in use”.
C. “In use” controls are tested along with the new lot controls with each new lot or new shipment of reagents. It is also acceptable to run previously positive and negative patient samples or CAP survey samples as parallel controls.
D. Record results on the appropriate Parallel Testing QC Worksheet.
E. If acceptable results are obtained, label the kit “ready for use” and initial and date the box.
F. If unacceptable results are obtained, repeat the test. If the results are still not acceptable, notify the supervisor, lead tech or manager for assistance.
G. STAT specimens should be sent to another site for testing until acceptable QC can be obtained.
H. If the test kit contains multiple components, do not mix components with another reagent kit of the same kind unless otherwise advised by the manufacturer.
I. Additional QC should be performed at a frequency according to the manufacturer's recommendations or based on individual testing procedures.
J. Parallel testing logs will be reviewed at least monthly by the lead medical technologist, or designee.

6. Results/Interpretation

All qualitative results must agree for the parallel testing to pass.

7. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

8. Procedure Development and Approval

Document Owner:

Larah Crawford (Sr Safety Specialist)

Writer(s):

Laura Bellon (Medical Technologist Lead)

Reviewer(s):

Lillian Reid (Medical Technologist Lead), Malak Saad (Medical Technologist Lead), Richard Quick (Medical Technologist Lead), Shani Kastl (Medical Technologist Lead), Tanya Williams (Medical Technologist Lead)

Approver:

Ashley Beesley (Mgr, Laboratory), Brittnie Berger (Dir Sr, Lab Operations), Caitlin Schein (Staff Physician), Christopher Ferguson (Dir, Laboratory Services), Helga Groat (Mgr, Laboratory), Jeremy Powers (Chief, Pathology), Kristen DiCicco (Mgr, Laboratory), Leah Korodan (Mgr, Division Laboratory), Muhammad Arshad (Chief, Pathology), Sarah Britton (VP, Laboratory Svcs), Stephanie Mullins (Supv, Laboratory)

9. Keywords

Not Set