HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Microbiology)		
Document:	Internal Policy and Procedure		
Title:	Clostridium Difficile Toxins A & B Detection		
Applies To:	All Laboratory Staff		
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1. PURPOSE:

1.1 To establish system and responsibilities for Clostridium Difficile Toxins A & B Detection in Stool.

2. DEFINITIONS:

General Information & Clinical Significance

2.1 Clostridium Difficile Toxins A & B is a diagnostic tool used to detect the presence of toxins A & B produced by the bacterium Clostridium difficile in stool samples. **Toxins are the hallmarks of the infection.**

2.2 Clostridium Difficile Toxins A & B are responsible for symptoms of C. difficile infection, which can range from diarrhoea to severe colitis, in rare cases, toxic mega colon or death.

2.3 Early & accurate diagnosis is crucial for timely treatment & prevention of complications.

2.4 C. difficile infection can also lead to hospital acquired infections, so testing is important for infection control & patient safety.

3. POLICY:

3.1 The This assay helps to diagnose C. difficile associated disease.

3.2 Unpreserved Stool specimens are the specimens of choice. Specimen should be collected and transported in an airtight container.

3.3 Specimen should be tested as soon as possible. For any expected delay, keep at 2-8^{0}C for maximum 4 days; otherwise keep it at -20^{0}C for longer storage (up to 3 freeze thaw cycles are accepted).

3.4 Any positive result will be notified to the ordering physician as it helps guide treatment decisions.

4. PROCEDURE:

4.1 Specimens:

4.1.1 Unpreserved stool specimen in an airtight container.

4.1.2 Any suspected delay in transport or processing, keep in the fridge (at 2-8 ^{0}C).

4.2 Processing of specimens:

4.2.1 Bring specimens & reagents to room temp. (20-25^{0}C) before processing.

4.2.2 Stool specimen must be mixed thoroughly before testing ,regardless of its consistency, to ensure representative specimen prior to testing.

4.2.3 Label one test tube for each patient, positive & negative control.

4.2.4 Add 200ul diluent & 150ul conjugate to each tube

4.2.5 Add 25ul or 2mm of stool to corresponding tube (according to its consistency) & one drop of each control. Mix well & let stand for 5 min. after that vortex diluted specimens for 10 sec.

4.2.6 Label Immune cards same as test tubes & add 150ul of the diluted specimen to each of the 2 sample ports of the corresponding test card. Same for positive & negative controls cards.

4.2.7 Incubate for 5 min at RT (till reaction well are completely wet), then add 150ul (3 drops) of wash buffer to each reaction port of each card.

4.2.8 When the wash buffer is completely absorbed, add 3 drops of the substrate to each reaction port.

4.2.9 Incubate for 5 min at RT, then read cards visually.

4.3 Interpretation of results:

4.3.1 Reading of Immune cards:

4.3.1.1 Positive test result: blue colour appear in both the test and control reaction ports

4.3.1.2 Negative test result: blue colour appear in control reaction ports Only. The test reaction port must be colourless. A negative test result indicates that the toxins are absent or below detection limit. The test is invalid if:

4.3.1.2.1 No detectable blue colour in the control reaction port.

4.3.1.2.2 A blue ring on the plastic frame surrounding the test port during the test procedure.

4.4 Quality control:

4.4.1 Each test card contains an internal control. In addition to positive control reagent & sample diluent can be used as negative control.

5. MATERIAL AND EQUIPMENT:

5.1 ImmunoCard Toxins A&B detection Kit; meridian bioscience

6. RESPONSIBILITIES:

6.1 The assigned technician/ technologist for microbiology lab.

6.2 The C. Pathology Specialist/ Consultant.

7. APPENDICES:

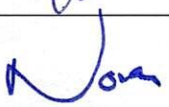
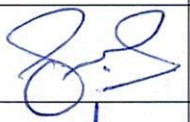
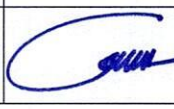
7.1 N/A

8. REFERENCES:

8.1 ImmunoCard Toxins A&B detection Kit; meridian bioscience

8.2 https://www.mayoclinic.org: Clostridium difficile infection – diagnosis & treatment.

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 01, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 05, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 07, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 15, 2025