Ministry of Health

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Directorate/Institution	The diagnostic laboratories services at the Directorate General of Specialized Medical Care (DGSMC) at Ministry of Health (MOH)
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Document Author	Mr. Saleh Muslem Sulaiman Alshukairi
Designation	Senior Laboratory Technologist A
Document Reviewer	1. Dr. Mahmoud Al Subhi 2. Ms. Zainab Al Hadhrami
Designation	1. Consultant microbiologist **2.** Senior Laboratory Technologist A
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Validated by		**Approved by**	
Name	Dr. Muna Habib	Name	Dr.Badryah Al Rashidi
Designation	Director Department Development & Conterol (DGQAC)	Designation	Director General of Primary Health Care
Signature		Signature	
Date	May 2023	Date	June 2023

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Member name	**Institution**	**Designation**
Dr.Mahmoud Al Subhi	Rustaq Hospital	Team Leader Consultant microbiologist
Ms. Zainab Al Hadhrami	Directorate General of Specialized Medical Care	Team Coordinator Senior technologist specialist A
Ms. Saleh Al Shukairi	Ibra Hospital	Senior technologist specialist A
Dr. Hanaa Al Auraimi	Royal Police of Oman Hospital	Consultant microbiologist
Dr. Nawal AL Kindi	Khoula Hospital	Consultant microbiologist
Dr. Al Warith Al Kharousi	Nizwa Hospital	Consultant microbiologist
Dr. Abdulrahman Al Mahrouqi	Ibri Hospital	Specialist microbiologist pathologist
Dr. Nada Al Tamimi	Al Massara Hospital	Consultant microbiologist
Dr. Wafaa Al Tamtami	Armed Forces Hospital	Specialist microbiologist pathologist

Acronyms:

CSF	Cerebral Spinal Fluid
ATCC	American Type Culture Collection
QC	Quality Control
SOP	Standard operating procedure
COSHH	Control of Substances Hazardous to Health
MSDS	Material Safety Data Sheet

1. Purpose:

This procedure provides instruction for identification of *Staphylococcus aureus* by latex test.

2. Scope:

This document is applicable to all laboratory technologist staff in Oman.

3. Definition:

3.1 Nosocomial infections (also known as Healthcare associated infections (HAIs)): a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent (s) or its toxin (s), with no evidence of infection was present at the time of admission. Infection is considered HAIs after the 3rd calendar day of admission.

4. Details procedure:

4.1 Pre- analytical stage:

4.1.1 Clinical background:

Staphylococcus aureus is a common pathogen in nosocomial infections and therefore exact identification is important to differentiate it from coagulase negative *Staphylococcus sp.* within few seconds. Rapid *S. aureus* agglutination test have been developed for routine diagnosis together with the tube coagulase test. There are many commercially available *S. aureus* agglutination tests kits.

4.1.2 Principle

Rapid latex agglutination test synthesized with fibrinogen and IgG detects bacterial aggregation of S. aureus surface antigens (clumping factor A and/ protein A, and/ capsular polysaccharide serotypes 5 and/ 8 or other structures).

4.1.3 Note:

All positive staph latex shall be confirmed by DNAse and coagulase tests.

4.1.4 Sample

- Sample type: well isolated 18-24 hours colonies.
- Sample source: solid culture medium.
- Amount of sample required, including minimum requirements: 2-3 colonies.
- Criteria for unacceptable samples and follow-up action: Culture older than 24 hours are not recommended.

4.1.5 Materials:

Reagents	Consumables/Supplies	Equipment
Staph Latex agglutination kit, Storage: 2-8°C.	All consumables are included with kit *Staphylococcus aureus* ATCC @ 29213. *Staphylococcus epidermidis* ATCC@ 12228	

4.1.6 Safety Precautions:

4.1.6.1 Refer to risk assessment, appropriate COSHH and MSDS documents.

4.1.6.2 Work with standard lab safety practice.

4.1.7 Quality Control:

4.1.7.1 Reagent shall be not expired, and labelled properly with expiry date once in use.

4.1.7.2 Use known positive and negative control with known ATCC strains.

- Positive Control: ATCC *Staphylococcus aureus* ATCC @ 29213.
- Negative Control: *Staphylococcus epidermidis* ATCC @ 12228.

4.1.7.3 Record quality control result on the quality control sheet (see appendix #1 Daily microbiology identification test quality control sheet).

4.2 Analytical stage:

4.2.1 Bring all reagents to room temperature before use.

4.2.2 Inspect the test latex for clumps, if clumps are available, don't use the reagent.

4.2.3 Don't use the kit if the reaction with control organism is not correct.

4.2.4 Stepwise instructions for performing the examination (Use operator's manual, Inserts).

4.3 Interpretation of the Results:

4.3.1 **Positive result:** Strong agglutination (clumps) occurs with the Staph test Latex Reagent. If you have performed a negative control there should be no agglutination with the Negative Control Latex Reagent. Delayed clumping should be ignored.

4.3.2 **Negative result:** No visible agglutination of the Staph test Latex Reagent particles.

4.3.3 **Inconclusive result:** If weak clumping or a non-specific reaction (stringiness) is present in the test circle after the manufacturer recommended time, the test should be repeated using a fresh subculture.

4.3.4 **Invalid result:** If the test isolates agglutinates with both the Staph Latex and Negative Control Latex, the test is invalid.

4.4 Method Performance Specifications:

4.4.1 Staph latex is sensitive and specific but false negative or false positive results can occur if inadequate amounts of culture or reagent are used.

4.4.2 Some rare isolates of staphylococci, notably *Staphylococcus hyicus* and *Staphylococcus interme*dius, may agglutinate the latex reagent.

4.4.3 Some streptococci and possibly other organisms that possess immunoglobulin binding factors and some species such as *Escherichia coli* may also agglutinate latex reagents non-specifically.

5. Responsibility:

5.1 Responsible staff shall:

5.1.1 To ensure the adherence to this procedure.

5.1.2 To perform and record the QC.

5.2 Quality manager /officer:

5.2.1 To follow up the implementation of the procedure.

5.2.2 To monitor regularly QC performance of the test and raise non-conformance with corrective action in case of any QC failure.

6. Document History and Version Control

Version	Description	Review Date
1	Initial Release	May 2026

7. References

Title of book/ journal/ articles/ Website	Author	Year of publication	Page
Manual of Clinical Microbiology	Versalovic J., Carrol K. C., Funke G., Jorgenesn J. H., Landry M. L., and Warnock D. W.	2011, 10th ed., vol. 2	
Rapid and Reliable Identification of *Staphylococcus aureus* by a Latex Agglutination Test, *Journal of Clinical Microbiology*	Essers L. and Radebold	1980; Vol. 12, No. 5	641-643
PROLEX™ STAPH LATEX KIT insert manual	Pro-Lab Diagnostic	2012	
Staphaurex kit insert manual	Remel	2011	
GCC IPC Surveillance Manual (Healthcare Associated Infections Surveillance Manual)	Hanan Balkhy & Aiman El-Saed Ramadan	2018	18

8. Annexes # 1 Daily microbiology identification test quality control sheet:

Test Name: Staph latex **Kit Manufacture Name: …….**

Reagent Lot No:-					**Reagent Open date:**		
Reagent Exp. Date							
Positive Control							
Negative Control							
Quality Control (Pass/Failed)							
Staff Number							
INITIALS & date							

Test Name: Staph latex **Kit Manufacture Name: ……**

Reagent Lot No:-					**Reagent Open date:**		
Reagent Exp. Date							
Positive Control							
Negative Control							
Quality Control (Pass/Failed)							
Staff number							
INITIALS & date							