



# **Table of Amendments in GAHAR Handbook for CLINICAL LABORATORIES ACCREDITATION STANDARDS**

**2025 Edition**

Publisher:  
General Authority for Healthcare Accreditation and Regulation

**Effective date:**  
1<sup>st</sup> September 2025

## APC Summary of Changes

| <b>GAHAR<br/>Clinical Labs<br/>2025</b>  | <b>GAHAR<br/>Clinical Labs<br/>2021</b>                           | <b><i>Details of changes</i></b>  |
|--|---|---|
| <b>APC.01</b><br><b>KW:</b> Accurate and complete information                  | <b>APC.03</b><br><b>KW:</b> Accurate and complete information     | <ul style="list-style-type: none"> <li>- <b>Modified Standard Statement:</b> (The laboratory provides GAHAR with accurate and complete information through <u>all steps</u> of the accreditation process).</li> <li>- <b>Modified EOC:</b> (<b>EOC.01:</b> The laboratory reports accurate and complete information to GAHAR during the <u>accreditation process</u>).</li> <li>- <b>Modified EOC:</b> (<b>EOC.03:</b> The laboratory reports within 30 days any structural changes in the laboratory scope of work of addition or deletion of services by more <u>than 20% of</u> its scope, building expansions, or demolitions).</li> <li>- <b>Add new EOC:</b> (<b>EOC.02:</b> The laboratory reports accurate and complete information to GAHAR in between accreditation visits).</li> </ul> |
| <b>APC.02</b><br><b>KW:</b> Professional standards during surveys              | <b>APC.05</b><br><b>KW:</b> Professional standards during surveys | <ul style="list-style-type: none"> <li>- <b>Modified EOC:</b> (<b>EOC.01:</b> The laboratory reports any conflict of interest to GAHAR with evidence <u>before or during surveys</u>).</li> <li>- <b>Added new EOC:</b> (<b>EOC.05:</b> The accredited laboratories use the GAHAR accreditation seal according to GAHAR's rules).</li> </ul>  |
| <b>APC.03</b><br><b>KW:</b> Sustaining compliance with accreditation standards | <b>APC.01</b><br><b>KW:</b> Sustaining registration requirements  | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (The GAHAR <u>accredited laboratory ensures continuous compliance</u> with the standards).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• (<b>EOC.01:</b> The laboratory establishes a process <u>for periodic assessment</u> of compliance with <u>accreditation standards</u>.)</li> <li>• (<b>EOC.02:</b> The laboratory acts on all feedback and reports received from GAHAR during the <u>accreditation period</u>).</li> <li>• (<b>EOC.03:</b> The laboratory <u>reacts to all GAHAR requirements</u> and reports in a timely manner.)</li> </ul> </li> <li>- <b>Added new EOC:</b> (<b>EOC.04:</b> The laboratory demonstrates (using monitoring tools) the</li> </ul>             |

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

compliance with GAHAR Safety Requirements  
and acts on identified gaps.)

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## PCC Summary of Changes

| <b>GAHAR Clinical<br/>Labs 2025</b>                                     | <b>GAHAR<br/>Clinical Labs<br/>2021</b>                                      | <b>Details of changes</b>  |
|---|--|--|
| <b>PCC.01</b><br>Multidisciplinary<br>client-centeredness               | <b>PCC.02</b><br><b>KW:</b><br>interdisciplinary<br>patient-<br>centeredness | <ul style="list-style-type: none"> <li>- <b>Modified Standard Statement:</b> (Client-centered culture is developed <b><u>by Multidisciplinary</u></b> collaboration.)</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved plan fulfilling the detailed practices for client-centered activities includes elements mentioned in intent from a) to f).</li> <li>• <b>(EOC.03:</b> Laboratory staff is <u>oriented</u> on a client-centeredness activities).</li> </ul> </li> <li>- <b>Added new EOCs:</b> <b>(EOC.05:</b> Laboratory leadership takes action to encourage staff participation in client-centeredness initiatives).</li> </ul> |
| <b>PCC.02</b><br><b>KW:</b> Client and<br>family rights.                | <b>PCC.02</b><br><b>KW:</b> Patient<br>and family<br>rights                  | <ul style="list-style-type: none"> <li>- <b>Added new EOC:</b> <b>(EOC.06:</b> Violations against clients' rights are reported and analyzed, and corrective action is taken).</li> </ul>   |
| <b>PCC.03</b><br><b>KW:</b> Client and<br>family<br>responsibilities.   | <b>PCC.03</b><br><b>KW:</b> Patient<br>and family<br>responsibilities        | <ul style="list-style-type: none"> <li>- <b>Rephrasing EOC:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.03:</b> Clients are informed of their responsibilities in a manner they can understand).</li> <li>• <b>(EOC.04:</b> Clients' responsibilities are posted in all public areas in the laboratory and visible to clients, families, and staff).</li> </ul> </li> <li>- <b>Added new EOC:</b> <b>(EOC.05:</b> Violations against clients' responsibilities are reported and analyzed, and corrective action is taken).</li> </ul>   |
| <b>PCC.04</b><br><b>KW:</b> Client and<br>health education<br>materials | <b>PCC.05</b><br><b>KW:</b> Patient<br>and family<br>education<br>materials. | <ul style="list-style-type: none"> <li>- <b>Rephrasing of Standard statement:</b> (The laboratory provides adequate client and health education materials).</li> <li>- <b>Updated EOC</b> (EOC.05) by merging (EOC.04 EOC.05)<br/>in laboratories 2021 edition.</li> </ul>   |
| <b>PCC.05</b><br><b>KW:</b> Informed<br>consent                         |  | <ul style="list-style-type: none"> <li>- <b>New Standard.</b></li> </ul>   |

| <b><i>GAHAR Clinical<br/>Labs 2025</i></b>              | <b><i>GAHAR<br/>Clinical Labs<br/>2021</i></b>           | <b><i>Details of changes</i></b>   |
|---|--|--|
| <b>PCC.06</b><br><b>KW:</b> Client and family feedback. | <b>PCC.06</b><br><b>KW:</b> Patient and family feedback. | <ul style="list-style-type: none"> <li>- <b>Rephrasing of EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.02:</b> Feedback from clients and families and other customers is received, analyzed, and interpreted in a timely manner.)</li> <li>• <b>(EOC.03:</b> The interpreted feedback is shared with the staff members concerned).</li> </ul> </li> <li>- <b>Add new EOC: (EOC.04:</b> The laboratory monitors the reported data on clients' and families' feedback and takes actions to control or improve the process as appropriate.</li> </ul> |
| <b>PCC.07</b><br><b>KW:</b> Complaints and suggestions. | <b>PCC.07</b><br><b>KW:</b> Complaints and suggestions.  | <ul style="list-style-type: none"> <li>- <b>Add new EOC: (EOC.02:</b> Staff is aware of complaints and suggestion policy).</li> <li>- <b>Modified EOC:</b> (EOC.04: Complaints and suggestions are investigated, analyzed by the laboratory, and <u>resolved</u> in an approved timeframe).</li> </ul>   |

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## LPR Summary of Changes

| <b>GAHAR<br/>Clinical Lab<br/>2025</b>                      | <b>GAHAR Clinical<br/>Lab 2021</b>                     | <b>Details of changes</b>  |
|---|--|--|
| <b>LPR.01</b><br><b>KW:</b> Laboratory services information | <b>TPR.01</b><br><b>KW:</b> Laboratory service manual. | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (The laboratory services and related information are provided for clients and users.)</li> <li>- <b>Rephrasing of EOC:</b> <b>(EOC.01:</b> Laboratory Service information describes the requirements as mentioned in intent from a) through p).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.03:</b> Laboratory service information is provided to clients (Service users) <u>in a manner they understand.</u>)</li> <li>• <b>(EOC.04:</b> Clients (Service users) are aware of the laboratory service information as per their need and according to laws and regulations.)</li> <li>• <b>(EOC.05:</b> Any changes in the laboratory service information are communicated to all laboratory staff members, and service users as per need.)</li> </ul> </li> <li>- <b>Add new EOC:</b> <b>(EOC.02:</b> Staff is aware of laboratory service information.)</li> </ul> |
| <b>LPR.02</b><br><b>KW:</b> Test requesting.                | <b>TPR.02</b><br><b>KW:</b> Test requesting            | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved procedure that describe the process of test request including elements mentioned in <u>the intent from a) through b).</u></li> <li>• <b>(EOC.03:</b> Request form includes all items mentioned in the intent from i) to ix).</li> </ul> </li> </ul>   |

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**Details of changes**

|  |  |  |
|--|--|--|
|  |  | <ul style="list-style-type: none"> <li>- <b>Add new EOC:</b>(EOC.02: Responsible staff is aware of requesting laboratory test procedure).</li> </ul>   |
| <b>LPR.03</b><br><b>KW:</b> Client <u>preparation</u> assessment   | <b>TPR.03</b><br><b>KW:</b> Patient assessment.                          | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (The laboratory performs preparation assessments before sampling.)</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved <u>procedure</u> to guide client <u>preparation assessment</u> before sampling process following testing algorithm and guidelines.)</li> <li>• <b>(EOC.02:</b> The responsible staff is qualified and aware of the process of client <u>preparation</u> assessment.</li> <li>• <b>(EOC.03:</b> The client <u>preparation assessment</u> is recorded in the client's request form.)</li> </ul> </li> </ul> |
| <b>LPR.04</b><br><b>KW:</b> Specimen identification and collection | <b>TPR.04</b><br><b>KW:</b> Specimen collection, Patient identification. | <ul style="list-style-type: none"> <li>- <b>Modified Standard Statement:</b> (The laboratory has a process for specimen identification and collection.)</li> <li>- <b>Modified EOC:</b> <b>(EOC.01:</b> The laboratory has an <u>approved procedure</u> that describe specimens' collection as mentioned in intent from a) through g).</li> <li>- <b>Add new EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.03:</b> Specimens labelling is performed according to the laboratory procedure.)</li> <li>• <b>(EOC.04:</b> Care of client and phlebotomy adverse incidents are managed.)</li> </ul> </li> </ul>   |
| <b>LPR.05</b><br><b>KW:</b> Specimen handling and transportation   | <b>TPR.05</b><br><b>KW:</b> Specimen handling and transportation.        | <ul style="list-style-type: none"> <li>- <b>Add new EOC:</b> <b>(EOC.03:</b> The procedure for specimens handling and transportation is followed within the laboratory).</li> </ul>  |

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**Details of changes**

|   |   |   |
|---|---|---|
| <b>LPR.06</b><br><b>KW:</b> Specimen reception and tracking   | <b>TPR.06</b><br><b>KW:</b> Specimen reception and tracking.  | <ul style="list-style-type: none"><li>- <b>Rephrasing of Standard statement:</b> (The laboratory has a process for specimen reception and tracking.)</li><li>- <b>Modified EOCs:</b><ul style="list-style-type: none"><li>- <b>(EOC.01:</b> The laboratory has <u>approved procedures</u> that describe process for specimen reception and tracking including elements mentioned in the intent from a) to e).</li><li>- <b>(EOC.03:</b> <u>All accepted</u>, rejected and suboptimal specimens are recorded including all data mentioned in the intent).</li><li>- <b>(EOC.05:</b> All specimens referred to other laboratories <u>are recorded</u>).</li></ul></li></ul> |
| <b>LPR.07</b><br><b>KW:</b> Pre-examination specimen storage. | <b>TPR.07</b><br><b>KW:</b> Pre-examination specimen storage. | <ul style="list-style-type: none"><li>- <b>Modified Standard Statement:</b> (The laboratory <u>defines</u> storage conditions for specimens during all pre-examination activities.).</li><li>- <b>Add new EOC: (EOC.02:</b> Responsible staff is aware about the proper storage condition of the specimen.)</li></ul>   |

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## LEP Summary of Changes

| <u><b>GAHAR Clinical<br/>Lab 2025</b></u>   | <u><b>GAHAR Clinical<br/>Lab 2021</b></u>  | <u><b>Details of changes</b></u>  |
|---|--|---|
| <b>LEP.01</b><br><b>KW:</b><br>Prepared/reconstituted reagents.                         | <b>TEX.05</b><br><b>KW:</b><br>Prepared/reconstituted reagents.                        | - <b>Modified</b> EOC:(EOC.01: Reagents/solutions labelling satisfying all requirements as mentioned in intent from a) to g).   |
| <b>LEP.02</b><br><b>KW:</b> Examination procedures selection.                           | <b>TEX.01</b><br><b>KW:</b> Validated examination procedure.                           | - <b>Rephrasing of Standard statement:</b> (The laboratory selects examination procedures which are fit for their intended use).  |
| <b>LEP.03</b><br><b>KW:</b> Verification / validation.                                  | <b>TEX.02</b><br><b>KW:</b> Verification / validation.                                 | - <b>Modified EOC:(EOC.01:</b> The laboratory has an <u>approved procedure</u> that describe the process for verification /validation of examination methods for all laboratory tests.)<br><br>- <b>Rephrasing of EOC: (EOC.03:</b> The laboratory follows verification/validation methods endorsed by guidelines.)   |
| <b>LEP.04</b><br><b>KW:</b> Biological reference interval and clinical decision values. | <b>TEX.03</b><br><b>KW:</b> Biological reference interval and clinical decision values | - <b>Rephrasing of Standard Statement:</b> (The laboratory defines and verifies biological reference intervals and defines clinical decision values for examination methods.)<br><br>- <b>Updated EOC (EOC.02) by merging two EOCs (EOC.02 &amp; EOC.04) in Clinical Labs 2021.</b><br>- <b>Add new EOCs: (EOC.04:</b> Biological reference intervals and clinical decision values are reviewed at least annually.) |
| <b>LEP.05</b><br><b>KW:</b> Examination procedure.                                      | <b>TEX.04</b><br><b>KW:</b> Examination procedure.                                     | <b>Modified EOCs:</b><br>• <b>(EOC.01:</b> The laboratory has a documented and <u>implemented</u> examination procedure for each analytical test method).<br><br>• <b>(EOC.03:</b> Each procedure includes all the required elements mentioned in the intent <u>from a) to k).</u>  |

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- (EOC.05: The laboratory examination procedures are reviewed at least annually by the authorized personnel).

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## LQC Summary of Changes

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>                    | <u><b>GAHAR Clinical<br/>Lab 2021</b></u>                 | <u><b>Details of changes</b></u>  |
|--|---|---|
| <b>LQC.01</b><br><b>KW:</b> Laboratory internal quality control. | <b>TEQ.01</b><br><b>KW:</b> Internal quality control plan | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (An internal quality control <u>process</u> is developed and implemented for all laboratory tests)</li> <li>- <b>Rephrasing of EOC: (EOC.05:</b> <u>Internal QC</u> records are retained for all laboratory tests for at least one year).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved <u>procedure</u> that describe the internal QC process of all laboratory tests fulfilling items <u>mentioned in the intent from a) to e).</u></li> <li>• <b>(EOC.03:</b> Responsible authorized laboratory personnel are competent in performing and <u>monitoring</u> internal QC).</li> </ul> </li> <li>- <b>Add new EOC: (EOC.04:</b> All quality control processes are performed according to the internal quality control procedure).</li> </ul> |
| <b>LQC.02</b><br><b>KW:</b> Quality control data review.         | <b>TEQ.02</b><br><b>KW:</b> Quality control data review.  | <ul style="list-style-type: none"> <li>- <b>Modified EOC:(EOC.01:</b> The laboratory has approved <u>procedures</u> that describe the process for reviewing the internal quality control data).</li> <li>- <b>Rephrasing of EOC: (EOC.02:</b> Authorized personnel reviews internal quality control process and checks data at regular intervals).</li> <li>- <b>Add new EOC:(EOC.04:</b> Evaluation of the effectiveness of the actions taken).</li> </ul>   |
| <b>LQC.03</b><br><b>KW:</b> Quality control result               | <b>TEQ.03</b>   | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (<u>Corrective / preventive</u> actions are taken upon quality control result violation(s).</li> </ul>   |

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**Details of changes**

violation,  
Corrective /  
preventive action.

**KW:** Quality control  
result violation,  
Corrective action.

- **Modified EOCs:**

- **(EOC.01:** The laboratory has approved procedures that describe the process for taking proper corrective / preventive actions to deficiencies identified).

- **(EOC.02:** The laboratory staff is aware of the corrective / preventive action for deficiencies identified.

- **(EOC.03:** The laboratory's corrective / preventive actions include elements mentioned in intent from a) through e).

- **(EOC.04:** Quality control data and error/incident logs are reviewed to identify the corrective / preventive actions to be taken).

**LQC.04**

**KW:** External  
quality program,  
proficiency testing  
(PT).

**TEQ.04**

**KW:** External quality  
program, proficiency  
testing.

- **Modified EOC:** **(EOC.02:** The laboratory participates in a PT program following the criteria mentioned in the intent from I) to V).

**LQC.05**

**KW:** Proficiency  
testing samples.

**TEQ.05**

**KW:** Proficiency  
testing samples.

- **Modified EOC:** **(EOC.01:** The laboratory has approved procedures that describe the process of proficiency testing requirements includes elements mentioned in intent from a) through e).

- **Add new EOC:** **(EOC.04:** Records of PT results are retained either as hard or soft copy).

**LQC.06**

**KW:** Alternative  
assessment  
procedure (AAPs).

**TEQ.06**

**KW:** Alternative  
assessment  
procedure.

- **Modified EOCs:**

- **(EOC.01:** The laboratory has an approved procedure that identify the method and the frequency of testing of AAPs includes elements mentioned in intent from a) to c).

- **(EOC.04:** Records of AAPs results and corrective / preventive actions are

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**Details of changes**

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reviewed by authorized person and  
retained for at least 1 year.

**LQC.07**

**KW:** Method  
Comparison.

**TEQ.07**

**KW:** Method  
Comparison.

**No change**

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## LPO Summary of Changes

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>                                       | <u><b>GAHAR<br/>Clinical Lab<br/>2021</b></u>  | <u><b>Details of changes</b></u>   |
|---|--|--|
| <b>LPO.01</b><br><b>KW:</b> Reporting results.                                      | <b>TPO.01</b><br><b>KW:</b> Reporting patient results.                               | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (The laboratory ensures accurate reporting).</li> <li>- <b>Modified EOC:</b>(<b>EOC.01:</b> The laboratory has <u>approved procedures</u> that describes the process of test results reporting as mentioned in intent from a) to d).</li> <li>- <b>Rephrasing of EOC:</b> (<b>EOC.05:</b> The laboratory reports including those from referral laboratories are reviewed to include elements mentioned in intent from i) through xiii).</li> <li>- <b>Add new EOCs:</b> <ul style="list-style-type: none"> <li>• (<b>EOC.02:</b> Authorized staff is aware about the content of the report).</li> <li>• (<b>EOC.03:</b> List of staff authorized to review the reports is available.</li> </ul> </li> </ul> |
| <b>LPO.02</b><br><b>KW:</b> Reviewing, release and retention of the reported result | <b>TPO.02</b><br><b>KW:</b> Reviewing, release and retention of the reported result. | <ul style="list-style-type: none"> <li>- <b>Rephrasing of Standard statement:</b> (The laboratory has a process for reviewing, releasing and retaining client results.)</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• (<b>EOC.01:</b> The laboratory has <u>approved procedures</u> that describe the process of reviewing, releasing, and retaining the reported results that includes elements mentioned in intent from a) to f).</li> <li>• (<b>EOC.03:</b> The retention process of a final laboratory report is <u>implemented</u> with easy retrieval).</li> </ul> </li> <li>- <b>Rephrasing of EOC:</b> (<b>EOC.04:</b> Test results are released to the authorized recipient).</li> </ul>  |
| <b>LPO.03</b><br><b>KW:</b> Storage, Retention and Disposal of specimen.            | <b>TPO.03</b><br><b>KW:</b> Storage, Retention and Disposal of specimen.             | <ul style="list-style-type: none"> <li>- <b>Rephrasing of Standard statement:</b> (The laboratory ensures safe storage, retention and disposal of post-examination specimens).</li> <li>- <b>Modified EOCs:</b></li> </ul>   |

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>     | <u><b>GAHAR<br/>Clinical Lab<br/>2021</b></u>     | <u><b>Details of changes</b></u>  |
|---|---|---|
|   |   | <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved <u>procedure</u> that describe the process for proper specimen storage and retention includes elements mentioned in intent from a) to f)</li> <li>• <b>(EOC.02:</b> Staff is aware of specimens' storage, retention <u>and disposal time</u>).</li> <li>• <b>(EOC.03:</b> The procedure of specimen storage, retention, and disposal is <u>implemented</u>.</li> </ul>  |
| <b>LPO.04</b><br><b>KW:</b> Turnaround time.      | <b>TPO.04</b><br><b>KW:</b> Turnaround time.      | <ul style="list-style-type: none"> <li>- <b>Add new EOC: (EOC.04:</b> Required specimens are easily retrieved.)</li> <li>- <b>Rephrasing of Standard Statement:</b> (Laboratory results are reported within the acceptable turnaround time.)</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved <u>procedure</u> defining each laboratory test's total turnaround time and means of measuring it).</li> <li>• <b>(EOC.02:</b> The laboratory monitors the reported data on reporting times for laboratory tests and takes <u>actions to control or improve the process as appropriate</u>).</li> <li>• <b>(EOC.03:</b> Delays in turnaround time are notified to <u>requestors/end-user</u>)</li> </ul> </li> </ul> |
| <b>LPO.05</b><br><b>KW:</b> Critical test result. | <b>TPO.05</b><br><b>KW:</b> Critical test result. | <ul style="list-style-type: none"> <li>- <b>Modified Standard Statement:</b> (Critical results are <u>communicated in time and documented</u> according to a defined process).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has <u>an approved</u> procedure of the critical test results reporting that describe the process of "write down "and «read-back» by the recipient).</li> </ul> </li> </ul>   |

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|  |   |             | <ul style="list-style-type: none"><li>• <b>(EOC.03:</b> The laboratory <u>defines lists</u> of critical values for specific tests).</li><li>• <b>(EOC.04:</b> All critical results are recorded within a <u>predefined timeframe</u>, includes elements mentioned in intent from a) through h).</li></ul>   |
|  |   |             | <ul style="list-style-type: none"><li>- <b>Add new EOC: (EOC.05:</b> The laboratory monitors the reported data on critical results and takes actions to control or improve the process as appropriate).</li></ul>   |
| <b>LPO.06</b><br><b>KW:</b> STAT results                             | <b>TPO.06</b><br><b>KW:</b> STAT results.               | <b>STAT</b> | <ul style="list-style-type: none"><li>- <b>Modified EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.01:</b> The laboratory has <u>an approved</u> procedure describing STAT testing process.)</li><li>• <b>(EOC.04:</b> The laboratory monitors the reported data on STAT turnaround time and <u>takes actions to control or improve the process as appropriate</u>).</li></ul></li></ul>  |
| <b>LPO.07</b><br><b>KW:</b> Amended / discrepant laboratory reports. | <b>TPO.07</b><br><b>KW:</b> Amended laboratory results. |             | <ul style="list-style-type: none"><li>- <b>Modified Standard Statement:</b> (Amended / <u>discrepant</u> laboratory reports are identified and maintained).</li><li>- <b>Modified EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.01:</b> The laboratory has an approved process for amended / <u>discrepant</u> reports.</li><li>• <b>(EOC.02:</b> Laboratory staff is aware and trained about process of amended / <u>discrepant</u> reports.</li><li>• <b>(EOC.06:</b> Amended / <u>discrepant</u> reports are modified by authorized personnel.</li></ul></li><li>- <b>Add new EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.03:</b> Amended report is identified and includes elements mentioned in intent from a) through e).</li></ul></li></ul> |



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- **(EOC.04:** Discrepant report is identified and includes elements mentioned in intent from I) through V).

**(EOC.05:** Amended / discrepant reports is reported to the authorized individual and proper actions are taken accordingly).

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

## EFS Summary of Changes

| <u><b>GAHAR Clinical<br/>Labs 2025</b></u>                             | <u><b>GAHAR Clinical<br/>Labs 2021</b></u>  | <u><b>Details of changes</b></u>  |
|--|---|---|
| <b>EFS.01</b><br><b>KW:</b> Laboratory environment and facility safety | <b>EFS.01</b><br><b>KW:</b> Laboratory environment and facility safety structure<br><br><b>EFS.02</b><br><b>KW:</b> Environmental and safety structure. | <ul style="list-style-type: none"> <li>- <b>Updated standards by merging two standards (EFS.01 &amp; EFS.02) in Clinical Labs 2021.</b></li> </ul>  |
| <b>EFS.02</b><br><b>KW:</b> Environment and facility safety monitoring | <b>EFS.01</b><br><b>KW:</b> Laboratory environment and facility safety structure  | <ul style="list-style-type: none"> <li>- <b>New Standard Statement:</b> (The laboratory environment and facility safety are overseen and monitored by a trained staff.)</li> <li>- <b>Add new EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory ensures the availability of a trained staff to oversee the environmental and facility safety activities.)</li> <li>• <b>(EOC.02:</b> The responsibilities of the EFS staff include the items mentioned in the intent from a) to d) in the intent.)</li> <li>• <b>(EOC.03:</b> The EFS staff is aware and perform its responsibilities.)</li> <li>• <b>(EOC.04:</b> The EFS staff reports on inspecting findings to the laboratory leadership at least quarterly.</li> </ul> </li> </ul> |
| <b>EFS.03</b><br><b>KW:</b> Fire and smoke safety plan, fire drill     | <b>EFS.03</b><br><b>KW:</b> Fire and smoke safety   | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved fire and smoke safety plan that includes the elements mentioned in the <u>intent from a) to f) and it is evaluated and updated annually</u>).</li> </ul> </li> </ul>   |

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- (EOC.03: The laboratory fire alarm systems are available, functioning, inspected, tested, and maintained on regular basis.)
- (EOC.04: The laboratory fire-fighting systems are available, functioning, inspected, tested, and maintained on regular basis.)
- (EOC.05: The laboratory guarantees safe evacuation through unobstructed and clearly signage for evacuation.
- **Added a new EOC:**(EOC.06: Fire drill is performed at least annually with the required documentation as mentioned in the intent from I) to V).

**EFS.04**

**KW:** Hazardous materials safety and waste management.

**EFS.05**

**KW:** Hazardous materials safety.

- **Modified** Standard Statement: (The laboratory ensures safe handling, storage, usage and transportation of hazardous materials and waste management.)
- **Modified** EOCs:
- (EOC.01: The laboratory has an updated hazardous material and waste management plan as mentioned in the intent from a) through k) in the intent.)
- (EOC.03: The laboratory ensures safe usage, handling, storage, availability of SDS and labelling of hazardous materials.)
- (EOC.04: The laboratory ensures safe, handling, storage, and labelling for waste occurs according to laws and regulations.
- (EOC.05: The laboratory has a documented investigation of spill or

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other hazardous materials related incidents.)

- **(EOC.06:** The plan is evaluated and updated annually with aggregation and analysis of necessary data and corrective actions acted upon.)

- **Add new EOC:(EOC.02:** Staff is trained on hazardous material and waste management plan.)

**EFS.05**  
**KW:** Safety and security management plan.

**EFS.06**  
**KW:** Safety program, Security plan.

- **Modified Standard Statement:** (The laboratory ensures a safe and secure work environment.).

- **Add new EOC: (EOC.01:** The laboratory has an approved updated plan to ensure a safe work environment including the items mentioned in the intent from a) to f) in the intent.)

- **Modified EOCs:**

- **(EOC.02:** The laboratory has an approved updated security plan including the elements mentioned in the intent from I) to VII).
- **(EOC.05:** Security measures are implemented.)
- **(EOC.06:** Safety and security plan/plans is/are evaluated and updated annually.)

- **Added a new EOCs:**

- **(EOC.03:** Staff is trained on safety and security plan/s.)
- **(EOC.04:** Safety measures and PPEs are available and used whenever indicated.

**EFS.06**

**EFS.07**

- **Modified EOCs:**

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**KW:** Utilities  
Management plan

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**KW:** Utilities  
Management

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- **(EOC.01:** The laboratory has an approved and updated utility management plan include the elements mentioned in the intent from a) to k).
  - **(EOC.03:** Records are maintained for utility systems inventory, testing, periodic preventive maintenance, and malfunction history).
  - **(EOC.04:** Critical utility systems are identified, and backup availability is ensured and evaluated on regular basis).
- **Added a new EOCs:**
- **(EOC.02:** The laboratory has trained staff members to oversee utility management).
  - **(EOC.05:** The plan is evaluated and updated annually with aggregation and analysis of necessary data).

**EFS.07**

**KW:** Pre-  
Construction risk  
assessment

**New standard**

**EFS.08**

**KW:** Disaster Plan

**EFS.04**

**KW:** Emergency  
preparedness plan

- **Rephrasing of Standard statement:** (Emergency preparedness plan addresses responding to disasters that have the potential of occurring within the geographical area of the laboratory.)
- **Modified EOC:** (EOC.01: There is an approved laboratory emergency preparedness plan includes the elements mentioned in the intent from a) to e).
- **Add new EOCs:**
  - **(EOC.04:** The laboratory demonstrates preparedness for

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identified emergencies based on risk assessment.)

- **(EOC.05:** The plan is evaluated at least annually with aggregation and analysis of necessary data.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

## EMS Summary of Changes

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>   | <u><b>GAHAR Clinical<br/>Lab 2021</b></u>  | <u><b>Details of changes</b></u>   |
|---|--|--|
| <b>EMS.01</b><br><b>KW:</b> Equipment management plan.  | <b>EMS.01</b><br><b>KW:</b> Equipment management plan.   | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved equipment management plan as mentioned in the intent from <u>a) through h) in the intent.</u>)</li> <li>• <b>(EOC.02:</b> <u>Relevant staff</u> is aware of the laboratory equipment plan and use.</li> </ul> </li> <li>- <b>Add new EOCs:</b> <b>(EOC.03:</b> Laboratory requisite equipment in accordance to pre-selection criteria as mentioned form I) to X) in the intent).</li> </ul> |
| <b>EMS.02</b><br><b>KW:</b> Equipment reception, installation, acceptance, <u>usage instructions.</u> | <b>EMS.02</b><br><b>KW:</b> Equipment reception, installation, acceptance.<br><br><b>EMS.03</b><br><b>KW:</b> Equipment instructions | <b>Updated Standard</b> by merging two Standards( <b>EMS.02</b> and <b>EMS.03</b> ) in Clinical Laboratories 2021.   |
| <b>EMS.03</b><br><b>KW:</b> Calibration plan.   | <b>EMS.04</b><br><b>KW:</b> Calibration plan.  | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has a current, approved calibration plan for all laboratory equipment with a predefined date of recalibration, that follows the manufacturer's calibration recommendations or <u>guidelines.</u>)</li> </ul> </li> </ul>  |

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|   |  |   |
|---|--|---|
|   |  | <ul style="list-style-type: none"> <li>• <b>(EOC.04:</b> Action taken <u>monitored</u> in case of deviation from acceptable criteria.</li> <li>- <b>Add new EOC: (EOC.02:</b> Relevant staff is aware of calibration plan.)</li> </ul>  |
| <b>EMS.04</b><br><b>KW:</b> Equipment maintenance, monitoring and failure management. | <b>EMS.05</b><br><b>KW:</b> Equipment maintenance and monitoring.<br><br><b>EMS.06</b><br><b>KW:</b> Equipment failure management. | <ul style="list-style-type: none"> <li>• <b>Updated Standard</b> by merging two Standards(<b>EMS.05</b> and <b>EMS.06</b>) in Clinical Laboratories 2021.</li> </ul>  |
| <b>EMS.05</b><br><b>KW:</b> Equipment records and files.                              | <b>EMS.07</b><br><b>KW:</b> Equipment records and files.   | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b><br/> <b>(EOC.02:</b> Equipment management program maintains records as mentioned in the intent from I) to VII).</li> <li>- <b>Add new EOC:(EOC.04:</b> Equipment file and records are kept up to date.)</li> </ul>   |
| <b>EMS.06</b><br><b>KW:</b> Retiring of equipment.                                    | <b>EMS.08</b><br><b>KW:</b> Retiring of equipment.   | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an approved <u>procedure</u> that describe the process for retiring laboratory equipment).</li> <li>• <b>(EOC.02:</b> Relevant staff is aware of equipment retiring process.)</li> </ul> </li> </ul> |

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition



## IPC Summary of Changes

| <u><b>GAHAR Clinical<br/>Labs 2025</b></u>                           | <u><b>GAHAR Clinical<br/>Labs 2021</b></u>  | <u><b>Details of changes</b></u>   |
|--|---|--|
| <b>IPC.01</b><br><b>KW:</b> IPC program, risk assessment, guidelines | <b>IPC.01</b><br><b>KW:</b> IPC program, risk assessment, guidelines.<br><br><b>IPC.04</b><br><b>KW:</b> Risk assessment. | <ul style="list-style-type: none"> <li>- <b>Updated Standard</b> by merging (<b>IPC.01</b> and <b>IPC.04</b>) in Clinical labs 2021.</li> </ul>  |
| <b>IPC.02</b><br><b>KW:</b> Hand Hygiene                             | <b>IPC.02</b><br><b>KW:</b> Hand Hygiene  | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• (<b>EOC.01:</b> The laboratory has approved Hand Hygiene policies and procedures based on current evidence-based guidelines that address all the elements mentioned in the intent <u>from a) to f).</u></li> <li>• (<b>EOC.02:</b> Laboratory professionals are <u>trained</u> on these policies and procedures.).</li> </ul> </li> <li>- <b>Add new EOCs:</b> <ul style="list-style-type: none"> <li>• (<b>EOC.03:</b> Hand hygiene is implemented according to the policy.)</li> <li>• (<b>EOC.06:</b> The laboratory monitors the reported data on the hand hygiene process and takes actions to control or improve the process as appropriate.)</li> </ul> </li> </ul> |
| <b>IPC.03</b><br><b>KW:</b> PPE, guidelines, Physical Barriers       | <b>IPC.03</b><br><b>KW:</b> PPE guidelines.   | <ul style="list-style-type: none"> <li>- <b>Modified EOC:</b> (<b>EOC.01:</b> The laboratory has approved <u>personal protective equipment (PPE)</u> policy and procedures, that address all the elements mentioned in the <u>intent from a) to e).</u></li> <li>- <b>Added a new EOCS:</b> <ul style="list-style-type: none"> <li>• (<b>EOC.02:</b> The choice of PPE to be purchased is based on standardized product specifications.)</li> </ul> </li> </ul>  |

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**Details of changes**

|   |   |  |
|---|---|--|
|   |   | <ul style="list-style-type: none"><li>• (EOC.04: All staff is trained on the proper way and sequence of donning and doffing of various PPE.)</li><li>• (EOC.05: Proper selection and use of PPE according to the client's suspected infection and/or procedure.)</li></ul>   |
| <b>IPC.04</b><br><b>KW:</b> Environmental cleaning, evidence-based guidelines | <b>IPC.05</b><br><b>KW:</b> Environmental cleaning & disinfection, evidence-based guidelines. | <ul style="list-style-type: none"><li>- <b>Modified Standard Statement:</b> (Environmental cleaning and disinfection activities are aligned with current <u>national/international</u> guidelines.)</li><li>- <b>Modified EOCs:</b><ul style="list-style-type: none"><li>• (EOC.01: The laboratory has approved cleaning and disinfection policy and procedures, that address all elements mentioned in the intent from I) to VII).</li><li>• (EOC.04: The cleaning technique and disinfectant of choice match the requirements of each cleaned <u>area according to the approved policy.</u>)</li></ul></li><li>- <b>Rephrasing of EOCs:</b><ul style="list-style-type: none"><li>• (EOC.02: <u>Laboratory Staff</u> members involved in environmental cleaning activities are trained on the policy.)</li><li>• (EOC.05: Clear instructions are available and followed for dealing with biological spills.)</li></ul></li><li>- <b>Added a new EOC:</b> (EOC.03: The laboratory identifies high-risk areas with different schedules for each area and includes all elements mentioned in the <u>intent from a) through c).</u></li></ul> |
| <b>IPC.05</b><br><b>KW:</b> Sterilization, laboratory autoclave, microbiology |   | <ul style="list-style-type: none"><li>- <b>New Standard.</b></li></ul>   |

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|---|--|----------------------------------|
| and cultures<br>media   |  |                                  |
| <b>IPC.06</b><br><b>KW:</b> Safe sampling<br>practices                          |  | - <b>New Standard.</b>           |
| <b>IPC.07</b><br><b>KW:</b> Respiratory<br>Hygiene Protocol,<br>cough etiquette |  | - <b>New Standard.</b>           |
| <b>IPC.08</b><br><b>KW:</b> Sterile<br>technique, Aseptic<br>technique          |  | - <b>New Standard.</b>           |
| <b>IPC.09</b><br><b>KW:</b> Biosafety and<br>biosecurity plan                   |  | - <b>New Standard.</b>           |

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

## OGM Summary of Changes

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>                              | <u><b>GAHAR<br/>Clinical Lab<br/>2021</b></u>   | <u><b>Details of changes</b></u>   |
|--|---|--|
| <b>OGM.01</b><br><b>KW:</b> Governing body Structure and responsibilities. | <b>OGM.01</b><br><b>KW:</b> Governance structure<br><br><b>OGM.02</b><br><b>KW:</b> Mission Statement.<br><br><b>OGM.03</b><br><b>KW:</b> Governing body responsibility.<br><br><b>OGM.04</b><br><b>KW:</b> Governing body performance.<br><br><b>OGM.05</b><br><b>KW:</b> Effective communication with governing body. | <b>Updated</b> Standard by merging Five Standards ( <b>OGM.01, OGM.02, OGM.03, OGM.04, OGM.05</b> ) in <b>Clinical Laboratories 2021 Edition.</b>  |
| <b>OGM.02</b><br><b>KW:</b> Laboratory Director.                           | <b>OGM.06</b><br><b>KW:</b> Laboratory Director.  | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (<u>A full-time</u> qualified director is appointed by the governing body to manage the laboratory according to applicable laws and regulations).</li> <li>- <b>Modified EOC:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> There is a job description for the laboratory director covering the requirements as mentioned in the <u>intent from a) to i).</u></li> </ul> </li> <li>- <b>Add new EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.03:</b> The laboratory identifies the proper communication channels between staff and laboratory head of department)</li> </ul> </li> </ul> |

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- **(EOC.04:** The governing body receives a periodic report from the laboratory head of department. about quality, client safety, and performance measures at least annually.).

**-Rephrasing of EOC:**

- (EOC.05: There is evidence of delegation of authority when needed.)

**OGM.03**  
**KW:** Strategic and operational Plans.

**OGM.07**  
**KW:** Strategic and operational Plans.

**- Rephrasing of EOCs:**

- **(EOC.01:** The laboratory has an approved strategic plan with defined goals and objectives.)
- **(EOC.03:** The strategic plan is regularly reviewed.)
- **(EOC.05:** Operational plans are reviewed at least annually.)

**OGM.04**  
**KW:** Laboratory head of departments

**OGM.08**  
**KW:** Laboratory leaders.

**- Updated standard by merging two standards (OGM.08 & OGM.10) in Clinical Labs 2021.**

**OGM.10**  
**KW:** Departmental management.

**OGM.05**  
**KW:** Billing system

**- New Standard.**

**OGM.06**  
**KW:** Ethical management

**OGM.11**  
**KW:** Ethical management

**- Modified Standard statement:** (The laboratory has an ethical management process.)

**- Rephrasing of EOC:** **(EOC.03:** Ethical issues are discussed and managed according to the approved code of ethics and resolved within defined time frame ).

**- Modified EOCs:**

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|  |  |  |
|--|--|--|
|  |  | <ul style="list-style-type: none"> <li>- <b>(EOC.01:</b> The laboratory has an approved policy for ethical management that addresses <u>at least a) to g) in the intent</u>).</li> <li>- <b>(EOC.02:</b> Laboratory staff is aware of the ethical <u>management policy</u> and approved code of ethics.)</li> <li>- <b>(EOC.04:</b> <u>Addressed</u> ethical issues are used for education and staff professional development.).</li> </ul>  |
| <b>OGM.07</b><br><b>KW:</b> Safety Culture             | <b>OGM.12</b><br><b>KW:</b> Safety Culture.            | <ul style="list-style-type: none"> <li>- <b>Modified Standard Statement:</b> (<u>Head of each department</u> create a culture of safety and quality within the laboratory).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>- <b>(EOC.01:</b> <u>Head of departments</u> participate in regular safety <u>audits</u>).</li> <li>- <b>(EOC.02:</b> <u>Head of departments</u> support quality and safety initiatives, monitoring, and improvement activities.)</li> <li>- <b>(EOC.03:</b> <u>Head of departments</u> creates a just culture to encourage reporting errors and near misses.).</li> </ul> </li> </ul> |
| <b>OGM.08</b><br><b>KW:</b> Positive Workplace Culture | <b>OGM.13</b><br><b>KW:</b> Positive Workplace Culture | <ul style="list-style-type: none"> <li>- <b>Modified EOC:</b> (<b>EOC.01:</b> The laboratory has an approved policy for positive workplace culture, that addresses <u>at least a) to f) from the intent</u>.)</li> <li>- <b>Add new EOC:</b> (<b>EOC.04:</b> There are communication channels between staff and Laboratory head of departments.)</li> </ul>  |
| <b>OGM.09</b><br><b>KW:</b> Staff health               | <b>WFM.10</b><br><b>KW:</b> Staff health               | <ul style="list-style-type: none"> <li>- <b>Rephrasing of Standard Statement:</b> (The laboratory has a staff health program that is monitored and evaluated annually according to laws and regulations.)</li> <li>- <b>Modified EOCs:</b></li> </ul>  |

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>                | <u><b>GAHAR<br/>Clinical Lab<br/>2021</b></u>      | <u><b>Details of changes</b></u>   |
|--|--|--|
|  |  | <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> There is a staff health program according to laws and regulations that cover <u>items a) to k) in the intent.</u>)</li> <li>• <b>(EOC.03:</b> Staff members are educated about the risks within the laboratory environment, their specific job-related hazards, <u>positive health promotion strategies,</u> and <u>periodic medical examinations.</u>)</li> </ul>  |
|  |  | <ul style="list-style-type: none"> <li>- <b>Add new EOC: (EOC.04:</b> All staff members are subject to the immunization program and to work restrictions according to evidence-based guidelines, laws and regulations, all test results and immunizations are recorded in the staff health record. )</li> </ul>  |
| <b>OGM.10</b><br><b>KW:</b> Community needs and Initiatives. | <b>OGM.15</b><br><b>KW:</b> Community Initiatives. | <ul style="list-style-type: none"> <li>- <b>Modified Standard Statement:</b> (Laboratory services <u>are designed to meet</u> community needs and comply with international, national, regional, and local community initiatives.)</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory <u>services</u> reflect alignment with international, regional, and/or national community initiatives).</li> <li>• <b>(EOC.02:</b> <u>All staff</u> is aware of laboratory community initiatives).</li> </ul> </li> <li>- <b>Add new EOC: (EOC.03:</b> The laboratory aligns the services provided with the assessed community health needs).</li> </ul> |

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

## SCM Summary of Changes

| <u><b>GAHAR<br/>Clinical Lab<br/>2025</b></u>                             | <u><b>GAHAR<br/>Clinical Lab<br/>2021</b></u>                | <u><b>Details of changes</b></u>  |
|---|--|---|
| <b>SCM.01</b><br>KW: Supply Chain Management                              | <b>SCM.01</b><br>KW: Laboratory Suppliers.                   | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (The laboratory defines supply chain management processes).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an <u>approved procedure</u> for supply chain management that addresses all elements mentioned in intent from <u>a) through e).</u></li> <li>• <b>(EOC.02:</b> <u>Responsible staff</u> is aware of the supply <u>chain management procedure.</u>)</li> <li>• <b>(EOC.04:</b> Suppliers are monitored and evaluated at <u>least annually.</u>)</li> </ul> </li> <li>- <b>Add new EOCs: (EOC.03:</b> The supply chain processes are recorded, monitored, and evaluated)</li> </ul>   |
| <b>SCM.02</b><br>KW: Supplies <u>selection</u> , reception and inspection | <b>SCM.02</b><br>KW: Supplies reception and inspection.<br>. | <ul style="list-style-type: none"> <li>- <b>Modified Standard statement:</b> (Laboratory <u>develops a process</u> for selecting, receiving, and inspecting reagents and supplies before being placed in service.)</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has approved procedures that describe the process of reagents, materials and <u>services selection</u>, reception, and inspection).</li> <li>• <b>(EOC.02:</b> Staff is aware of reagents / supplies <u>selection</u>, reception and inspection process and corrective actions when needed.).</li> <li>• <b>(EOC.04:</b> Records for reception <u>and inspection</u> process includes items mentioned in intent from a) to d).</li> </ul> </li> </ul> |



| <b><u>GAHAR<br/>Clinical Lab<br/>2025</u></b>                    | <b><u>GAHAR<br/>Clinical Lab<br/>2021</u></b>                   | <b><u>Details of changes</u></b>   |
|--|---|--|
| <b>SCM.03</b><br><b>KW:</b> Inventory management.                | <b>SCM.03</b><br><b>KW:</b> Inventory management.               | <ul style="list-style-type: none"> <li>- <b>Modified EOC:(EOC.01:</b> The laboratory has an <u>approved procedure</u> that describes the inventory management system.)</li> <li>- <b>Add new EOC: (EOC.02:</b> Staff is aware of the inventory management procedure.)</li> </ul>   |
| <b>SCM.04</b><br><b>KW:</b> Supplies requesting and dispatching. | <b>SCM.04</b><br><b>KW:</b> Supplies requesting and dispatching | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory <u>has approved procedures</u> that describe the process of requesting and dispatching reagents and supplies includes elements mentioned in intent from a) to e).</li> <li>• <b>(EOC.02:</b> <u>Responsible staff</u> is aware of reagent requesting and dispatching process).</li> </ul> </li> <li>- <b>Add new EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.03:</b> Records are updated after each dispatching process).</li> <li>• <b>(EOC.04:</b> Laboratory rules for dispatching material are followed.)</li> </ul> </li> </ul> |
| <b>SCM.05</b><br><b>KW:</b> Contracted services.                 | <b>SCM.05</b><br><b>KW:</b> Contracted services.                | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> There is a list of all contracted <u>providers</u>).</li> <li>• <b>(EOC.04:</b> There are evaluation criteria for monitoring the contracted services includes elements mentioned in intent <u>from a) to e).</u></li> <li>• <b>(EOC.05:</b> Each contract is evaluated at least annually to determine if it should be renewed, <u>amended</u> or terminated).</li> </ul> </li> </ul>   |
| <b>SCM.06</b><br><b>KW:</b> Referral laboratory                  | <b>SCM.06</b><br><b>KW:</b> Referral laboratory.                | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has an <u>approved procedure</u> that describe process for selection and evaluation of referral laboratories).</li> <li>• <b>(EOC.03:</b> The selected laboratory meets the selection criteria includes elements mentioned in intent <u>from a) to f).</u></li> </ul> </li> </ul>   |

**GAHAR**  
**Clinical Lab**  
**2025**

**GAHAR**  
**Clinical Lab**  
**2021**

**Details of changes**

- 
- **Add new EOC:(EOC.06:** The referral laboratory is evaluated before, during, and upon renewal of the contract or at least annually, and actions are taken).

## WFM Summary of Changes

| <u><b>GAHAR Clinical<br/>Labs 2025</b></u>                 | <u><b>GAHAR Clinical<br/>Labs 2021</b></u>                         | <u><b>Details of changes</b></u>   |
|--|--|--|
| <b>WFM.01</b><br>KW: Workforce<br>Laws and<br>regulations. | <b>WFM.01</b><br>KW: Workforce<br>manual, Laws and<br>regulations. | <ul style="list-style-type: none"> <li>- <b>Added a new EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory identifies all applicable laws, regulations, and norms that guide workforce management.)</li> <li>• <b>(EOC.04:</b> <u>The workforce is managed</u> and developed according to applicable laws, regulations, and <u>norms that guide workforce management.</u></li> </ul> </li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.02:</b> Responsible staff members are aware of <u>laws, regulations, and norms that guide workforce management.</u>)</li> </ul> </li> </ul> |
| <b>WFM.02</b><br>KW: Staffing plan.                        | <b>WFM.02</b><br>KW: Staffing plan.                                | <ul style="list-style-type: none"> <li>- <b>Modified</b> Standard Statement: (The laboratory staffing plan matches the laboratory's mission and professional practice recommendations.)</li> <li>- <b>Modified</b> EOC: <b>(EOC.03:</b> The staffing plan identifies the estimated needed staff numbers including <u>independent practitioner</u>, skills and to meet the laboratory needs.)</li> </ul>  |
| <b>WFM.03</b><br>KW: Recruitment<br>process                | <b>WFM.03</b><br>KW: Recruitment                                   | <ul style="list-style-type: none"> <li>- <b>Modified</b> Standard Statement: (The laboratory implements a uniform recruitment process <u>according to laws and regulations.</u>)</li> <li>- <b>Added a new</b> EOC: <b>(EOC.04:</b> The recruitment process is uniform across the laboratory for similar types of jobs.)</li> </ul>  |
| <b>WFM.04</b><br>KW: Job<br>Description.                   | <b>WFM.04</b><br>KW: Job<br>Description.                           | <ul style="list-style-type: none"> <li>- <b>Rephrasing</b> of Standard Statement: (Job descriptions address each position's requirements and responsibilities.)</li> </ul>   |

**GAHAR Clinical  
Labs 2025**

**GAHAR Clinical  
Labs 2021**

**Details of changes**

- Updated (EOC.01) by merging two EOCs(EOC.01 & EOC.02) in Clinical Labs 2021 edition.
- Added a new EOCs:
  - (EOC.02: Job descriptions address each position's responsibilities, required qualifications, and reporting structure.
  - (EOC.04: The job description is signed by the staff and kept in the staff's file.
- Modified EOC: (EOC.03: On assignment, the job description is discussed with staff members, including independent practitioners.)

**WFM.05**  
**KW:** Verifying  
credentials, clinical  
privilege

**WFM.12**  
**KW:** Verifying  
credentials

- **Modified** Standard statement: (Staff credentials are verified and clinical privilege are granted to qualified staff.)
- **Modified** EOC: (**EOC.01:** Required credentials for each position are collected and kept in staff files including independent practitioners' files.)
- **Added a new EOCs:**
  - (**EOC.05:** Clinical privileges are accessible and granted to qualified staff when needed.)
  - (**EOC.06:** Clinical privileges are documented in the staff file including renewal when applicable.)

**WFM.06**  
**KW:** Staff Files.

**WFM.11**  
**KW:** Staff Files.

- **Modified EOC:**
  - (**EOC.01:** The laboratory has an approved policy to maintain and standardize staff files as mentioned in intent from a) through f).

**GAHAR Clinical  
Labs 2025**

**GAHAR Clinical  
Labs 2021**

**Details of changes**

|  |   |   |
|--|---|---|
| <b>WFM.07</b><br><b>KW:</b> Orientation Program.         | <b>WFM.05</b><br><b>KW:</b> Orientation Program.          | <ul style="list-style-type: none"><li>• <b>(EOC.05:</b> Staff files are <u>retained</u> and disposed as per laboratory policy, laws, and regulations</li></ul>  |
|  |   | <ul style="list-style-type: none"><li>- <b>Modified EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.01:</b> <u>A general orientation program is performed, and it includes at least the elements from a) through d).</u></li><li>• <b>(EOC.04:</b> <u>All new staff members, including contracted and outsourced staff, attend the orientation program.)</u></li><li>• <b>(EOC.05:</b> <u>There is evidence that each staff member has completed the orientation program, which is recorded in their file.)</u></li></ul></li><li>- <b>Added a new EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.02:</b> A department orientation program is performed, and it includes at least the elements from e) through h).</li><li>• <b>(EOC.03:</b> A job-specific orientation program is performed and it includes at least the elements from i) through k).</li></ul></li></ul> |
| <b>WFM.08</b><br><b>KW:</b> Continuing Education Program | <b>WFM.06</b><br><b>KW:</b> Continuous Education Program. | <ul style="list-style-type: none"><li>- <b>Modified EOC: (EOC.01:</b> The laboratory has a training and continuing education program for all staff categories that include elements mentioned in <u>intent from a) through k).</u></li><li>- <b>Added a new EOC: (EOC.04:</b> The educational program is based on the training needs assessment of the staff.)</li></ul>  |
| <b>WFM.09</b><br><b>KW:</b> Competency assessment.       | <b>WFM.07</b><br><b>KW:</b> Competency assessment.        | <ul style="list-style-type: none"><li>- <b>Modified</b> Standard statement: (The laboratory develops a process for staff competency assessment.)</li></ul>  |

**GAHAR Clinical  
Labs 2025**

**GAHAR Clinical  
Labs 2021**

**Details of changes**

|   |   |   |
|---|---|---|
|   |   | <ul style="list-style-type: none"><li>- <b>Added a new EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.02:</b> Competency assessment aligns with the assigned job and includes elements mentioned in the intent from a) through f).</li><li>• <b>(EOC.04:</b> There is evidence of employee feedback on competency evaluation.)</li></ul></li></ul>  |
| <b>WFM.10<br/>KW: Staff<br/>performance<br/>evaluation.</b> | <b>WFM.08<br/>KW: Staff<br/>performance<br/>evaluation.</b> | <ul style="list-style-type: none"><li>- <b>Modified</b> Standard statement: (Staff performance is regularly evaluated.)</li><li>- <b>Added a new EOCs:</b><ul style="list-style-type: none"><li>• <b>(EOC.01:</b> Performance evaluation is performed at least annually for each staff member.)</li><li>• <b>(EOC.02:</b> Head of departments carries out performance evaluations.)</li><li>• <b>(EOC.03:</b> Performance evaluation is based on the job description.)</li><li>• <b>(EOC.04:</b> There is evidence of employee feedback on performance evaluation.)</li></ul></li></ul> |
| <b>WFM.11<br/>KW: Working<br/>Hours</b>                     | <b>WFM.09<br/>KW: Staff burnout<br/>and turnover.</b>       | <ul style="list-style-type: none"><li>- <b>Modified</b> Standard statement: (The laboratory ensures safe and efficient working hours.)</li><li>- <b>Modified</b> EOC: <b>(EOC.03:</b> The staff schedules ensure suitable working hours, planned rest times, <u>maternity protection, and arrangements for breastfeeding according to laws and regulations.</u>)</li></ul>  |

**GAHAR Clinical  
Labs 2025**

**GAHAR Clinical  
Labs 2021**

**Details of changes**

- **Added a new EOC: (EOC.04:** When working hours exceed the approved limits, measures are taken to ensure staff safety and satisfaction.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

## IMT Summary of Changes

| <u><b>GAHAR<br/>Clinical Labs<br/>2025</b></u>  | <u><b>GAHAR Clinical<br/>Labs 2021</b></u>                            | <u><b>Details of changes</b></u>  |
|---|---|---|
| <b>IMT.01</b><br><b>KW:</b><br>Documentation management system.                         | <b>IMT.01</b><br><b>KW:</b> Documentation management system.          | <ul style="list-style-type: none"> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> The laboratory has approved procedures that describe the process for creating, formatting, and reviewing of documents includes elements mentioned in <u>intent from a) to h).</u></li> <li>• <b>(EOC.03:</b> Reviewing of selected <u>documents</u> that comply with the mentioned procedure are <u>conducted within defined timeframes).</u></li> </ul> </li> </ul>  |
| <b>IMT.02</b><br><b>KW:</b> Record management system.                                   | <b>IMT.02</b><br><b>KW:</b> Record management system.                 | <ul style="list-style-type: none"> <li>- <b>No Change.</b></li> </ul>   |
| <b>IMT.03</b><br><b>KW:</b> LIS management.   | <b>IMT.03</b><br><b>KW:</b> LIS management.                           | <ul style="list-style-type: none"> <li>- <b>Add new EOC: (EOC.05:</b> Confidentiality of client information is maintained according to laws and regulations).</li> </ul>  |
| <b>IMT.04</b><br><b>KW:</b> LIS security, unauthorized <u>access</u> and modifications. | <b>IMT.04</b><br><b>KW:</b> LIS security, unauthorized modifications. | <ul style="list-style-type: none"> <li>- <b>Modified</b> Standard statement: (Information management security is defined, tested periodically and data are protected from unauthorized <u>access</u>, modification and update.).</li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>- <b>(EOC.01:</b> The laboratory has an approved policy and procedure that describe the process for information management security including accessibility, modification and updates to client data includes elements mentioned in intent from <u>a) to h).</u></li> <li>- <b>(EOC.04: <u>Authorization list</u></b> is present for staff based on their responsibilities.</li> </ul> </li> </ul> |



**GAHAR**  
**Clinical Labs**  
**2025**

**GAHAR Clinical**  
**Labs 2021**

**Details of changes**

- **Add new EOC:**

- **(EOC.03:** The laboratory that has computer-based information management system (LIS), fulfilling all elements mentioned in the intent from I) to III).
- **(EOC.05:** There is a signed confidentiality agreement in each staff member's personal file.)
- **(EOC.06:** Procedures are followed if confidentiality or security of information has been breached.)

**IMT.05**  
**KW:** LIS validation.

**IMT.05**  
**KW:** LIS validation.

- **Updated standard by merging two standards (IMT.05 & IMT.08) in clinical labs 2021.**

**IMT.08**  
**KW:** Calculated values.

**IMT.06**  
**KW:** Maintenance program, Contingency plan.

**IMT.06**  
**KW:** Maintenance program, Contingency plan.

- **No change.**

**IMT.07**  
**KW:** LIS User manual

**IMT.07**  
**KW:** LIS User manual

- **Modified EOC: (EOC.02:** Laboratory staff is trained on the LIS proper use according to their responsibilities).

**IMT.08**  
**KW:** Data transfer and Interface.

**IMT.09**  
**KW:** Data transfer and Interface.

**No change.**

**IMT.09**

**IMT.10**

- **No change.**

**GAHAR**  
**Clinical Labs**  
**2025**

**GAHAR Clinical**  
**Labs 2021**

**Details of changes**

**KW:** Auto  
verification.

**KW:** Auto  
verification.

**IMT.10**  
**KW:** Data storage  
and retrieval.

**IMT.11**  
**KW:** Data storage  
and retrieval.

- **Add new EOC: (EOC.04:** The laboratory backup system is implemented.)

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

## QPI Summary of Changes

| <u><b>GAHAR Clinical<br/>labs 2025</b></u>           | <u><b>GAHAR Clinical<br/>labs 2021</b></u>   | <u><b>Details of changes</b></u>  |
|--|--|---|
| <b>QPI.01</b><br><b>KW:</b> Quality improvement plan | <b>QPI.01</b><br><b>KW:</b> Quality management program.<br><br><b>QPI.02</b><br><b>KW:</b> Quality management qualified individual.<br><br><b>QPI.09</b><br><b>KW:</b> performance improvement plan. | <ul style="list-style-type: none"> <li>- <b>Updated</b> Standard (QPI.01) by merging Three standards (QPI.01, QPI.02, and QPI.09) in Labs edition 2021.</li> </ul>  |
| <b>QPI.02</b><br><b>KW:</b> Performance measures     | <b>QPI.03</b><br><b>KW:</b> Performance measures   | <ul style="list-style-type: none"> <li>- <b>Modified</b> Standard statement: <b>(Performance measures are <u>identified, defined and monitored</u> for all significant processes.)</b></li> <li>- <b>Modified EOCs:</b> <ul style="list-style-type: none"> <li>• <b>(EOC.01:</b> <u>There is a list of</u> the laboratory measures includes the items mentioned in the <u>intent from a) to e).</u></li> <li>• <b>(EOC.03:</b> Staff responsible for the collection, interpretation, and/or use of performance measurement is aware of its definition and <u>identity card contents).</u></li> <li>• <b>(EOC.04:</b> The relevant performance measures <u>are monitored frequently.)</u></li> <li>• <b>(EOC.05:</b> Results of measures analysis are regularly reported to the governing body and to those accountable for <u>improvement and action taking.)</u></li> </ul> </li> <li>- <b>Add new EOC:</b> <b>(EOC.02:</b> There is an <u>approved identity card</u> for each selected performance measure.)</li> </ul> |

**GAHAR Clinical  
labs 2025**

**GAHAR Clinical  
labs 2021**

**Details of changes**

**QPI.03**  
**KW:** Data  
aggregation,  
analysis, and  
validation

**QPI.04**  
**KW:** Data  
management,  
aggregation and  
analysis.

- **Modified Standard statement:** (The laboratory has a process in place for data aggregation, analysis, and validation.)
- **Modified EOC: (EOC.01:** There is a written process for data review and validation as mentioned in the intent from I) through VII).

**QPI.04**  
**KW:** Internal  
assessment and  
nonconformity  
management.

**QPI.05**  
**KW:** Internal  
assessment  
program.

**QPI.06**  
**KW:** Nonconformity  
management.

- **Updated Standard by merging** (QPI.05 and QPI.06) in Clinical Laboratories 2021 Edition.

**QPI.05**  
**KW:** Risk  
Management  
plan/program.

**QPI.07**  
**KW:** Risk  
Management  
plan/program.

- **Modified EOCs:**
  - **(EOC.01:** The laboratory has a management plan/ program that include the elements mentioned in the intent i).
  - **(EOC.02:** Actions are taken according to the results of risk assessment.)
  - **(EOC.05:** The laboratory has a proactive risk reduction tool for at least one high process annually.)
- **Added a new EOCs:**
  - **(EOC.03:** Results of risk management activities are communicated to the governing body at least quarterly).
  - **(EOC.04:** The risk management plan and the risk register are evaluated and updated at least annually or when indicated.)

**QPI.06**  
**KW:** Incident  
Reporting System.

**QPI.08**  
**KW:** Incident  
reporting system

- **Rephrasing of Standard statement:** (The laboratory develops an incident-reporting system.)

- **Modified EOCs:**
  - **(EOC.01:** The laboratory has an approved incident-reporting system that includes items from a) through f) in the intent).
  - **(EOC.03:** Reported incidents are investigated, and corrective / preventive actions are taken to close gaps in services in a timely manner.
- **Rephrasing of EOC:** **(EOC.04:** The laboratory provides immediate and ongoing support to clients and staff who are affected by adverse events.)
- **Added a new EOCs:**
  - **(EOC.05:** All sentinel events are investigated, and corrective/preventive actions are taken based on identified root cause analysis.)
  - **(EOC.06:** All sentinel events are communicated to GAHAR within two working days of the event or becoming aware of the event.).

**QPI.07**

**KW:** Sustained  
improvement activitie

- **New Standard.**

Throughout all chapters, 'patient(s)' was changed to 'client(s)' in the Laboratories 2025 edition

