**Immunohematology Reagent Quality Control**

- **Iranian Blood Transfusion Organization**

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**Introduction**

- It is the responsibility of the national blood program to provide an adequate supply of blood for all patients requiring blood and to ensure the quality of processes and activities that prepares the blood and blood products for clinical use (WHO)
The strategies for achieving this are:

- Establishment of a well-organized, nationally-coordinated blood transfusion service (IBTO)

- Availability of appropriate policies, standards and activities (Quality Management) to ensure safe blood transfusion by testing all donated blood and patients samples receiving blood transfusions including screening for transfusion—transmissible infections, blood grouping and compatibility testing
Goals of Quality Managements

- Detection and prevention of errors with an emphasis on prevention
- Implementation of effective process and system controls
- Improve test credibility
Quality Management

in

Immunohematology Laboratory and Hospital Blood Bank

Determines Quality policy objectives and responsibilities
implemented by

Quality system

Procedures, processes, resource for

<table>
<thead>
<tr>
<th>Quality Planning</th>
<th>Quality Control</th>
<th>Quality Assurance</th>
<th>Quality Improvement</th>
</tr>
</thead>
</table>

**Immunohematology Reagent Quality Control**

**Introduction**

*Goal*: is to establish that reagents are reacting appropriately each day of use or per run by the user.

*Controls*: monitor the stability of methods or test systems.

*QC players*: manufacturer and the end user

*When to perform QC?*
At the time of receipt to the facility and ends when the lot number used up or is out dated.
Immunohematology Reagent Quality Control

Circumstances for unexpected results:

• extreme shipping conditions
• improper storage temperatures
• contamination of opened vials
• hemolysis of cellular reagents
• turbidity of blood group reagents
• equipment maintenance
• technical errors

Document: the unaccepted results for investigation of incident must be recorded for follow ups and corrective actions.
Immunohematology Reagent Quality Control

• Standard Operating procedures
  ✓ Standards and regulatory requirements
  ✓ Receipts
  ✓ Testing
  ✓ Frequency of testing
  ✓ Retesting
  ✓ Acceptable criteria
  ✓ Corrective actions
  ✓ Responsibility

• Regulatory
  (FDA, CE, WHO, Governmental-MOH & Organizational IBTO certifying bodies)
  ✓ The laboratory must utilize test methods, equipments, instrumentation, reagents, materials and supplies that provide accurate and reliable test results by meeting requirements
Immunohematology Reagent Quality Control

• Safety
• Tracking of Reagents by End-user
  ✓ Receipt
  ✓ Storage
  ✓ Use

• Frequency of testing requirements

<table>
<thead>
<tr>
<th>Reagent QC</th>
<th>Positive / Negative Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABO anti sera</td>
<td>Each day of use</td>
</tr>
<tr>
<td>Rh(D) anti sera</td>
<td>Each day of use</td>
</tr>
<tr>
<td>Other anti sera</td>
<td>Each day of use</td>
</tr>
<tr>
<td>AHG (IgG)</td>
<td>Each day of use</td>
</tr>
<tr>
<td>ABO reagent cells</td>
<td>Each day of use</td>
</tr>
<tr>
<td>ABS (antibody screening cells)</td>
<td>Each day of use</td>
</tr>
</tbody>
</table>
Corrective action

1. Review procedures used
2. Search for recent events that could cause change
   ✓ New reagent kit or lot number
   ✓ New control bottle
   ✓ Instrumentation component replacement
   ✓ Instrument maintenance
   ✓ Instrument moved

3. Examine the environment conditions
4. Prepare new control material
5. Follow manufacturers trouble shooting guide
6. Contact manufacturers of
   ✓ Instrumentation
   ✓ Reagent material
   ✓ Control material
7. Use three-cycle approach

- Documentation
  - cGMP requires documentation of each step in a process either in writing or through a validated computer system.

- Procedures
  Blood bank regents are divided into four categories
  1. Serologic blood bank reagents
  2. Soluble substance
  3. Other test methods
  4. Infectious disease testing
### Immunohematology Reagent Quality Control

<table>
<thead>
<tr>
<th>Reagent</th>
<th>معرف شرکت سازنده</th>
<th>Manufacturer</th>
<th>Lot #</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-A</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Anti-B</td>
<td></td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Anti-A/B</td>
<td></td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Anti-D(1)</td>
<td></td>
<td></td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Rh Control</td>
<td></td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Anti-D(2)</td>
<td></td>
<td></td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>Dilute Anti-D</td>
<td>IBTO</td>
<td></td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Enhancement-media</td>
<td></td>
<td></td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Anti-human globulin</td>
<td></td>
<td></td>
<td>19</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Reagent</th>
<th>IgG Control Cells</th>
<th>Lot #</th>
<th>EXP. date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARG PS1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARG PS2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-IgG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Cod</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin 0%</td>
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</tbody>
</table>

99. BP.013 FMR.001
# Immunohematology Reagent Quality Control

## Iranian Blood Transfusion Organization

### Immunohematology Reference Laboratory

**Worksheet for Special Antigen Tests for Patient & Controls**

<table>
<thead>
<tr>
<th>Date</th>
<th>POS/NEG Controls</th>
<th>Anti-Sera Spec/Patient Unit No.</th>
<th>Direct Test</th>
<th>INDIRECT TEST</th>
<th>INTERPRETATION Ag Pos/Ag Neg</th>
<th>Tech.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MFC NAME Lot No. EXP DATE IS INCUBATION AIG CC</td>
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</tbody>
</table>

- با توجه به سازنده و نوع محلول و درجه حرارت انکووانسیون میرایشند قبل از استفاده از آنتی سرم دستورالعمل محشر معرف را مطالعه کنید.
- برای هر یک از آنتی سرم‌ها آزمایش کنترل مثبت و منفی الکل است.

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صفحه 1 از ١