§ 493.927 General immunology.

(a) Program content and frequency of challenge. To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS’ option, may be provided to HHS or its designee for on-site testing.

(b) Challenges per testing event. The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure

- Alpha-l antitrypsin
- Alpha-fetoprotein (tumor marker)
- Antinuclear antibody
- Antistreptolysin O
- Anti-human immunodeficiency virus (HIV)
- Complement C3
- Complement C4
- Hepatitis markers (HBsAg, anti-HBc, HBeAg)
- IgA
- IgG
- IgE
- IgM
- Infectious mononucleosis
- Rheumatoid factor
- Rubella
- Hepatitis markers (HBsAg, anti-HBc, HBeAg)

(c) Evaluation of a laboratory’s analyte or test performance. HHS approves only those programs that assess the accuracy of a laboratory’s responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory’s response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory’s response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(3) The criterion for acceptable performance for quantitative syphilis serology tests is the target value ±1 dilution.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

\[
\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}
\]

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value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

<table>
<thead>
<tr>
<th>Analyte or test</th>
<th>Criteria for acceptable performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-1 antitrypsin</td>
<td>Target value ±3 SD. Target value ±3 SD.</td>
</tr>
<tr>
<td>Alpha-fetoprotein (tumor marker)</td>
<td>Target value ±2 dilutions or positive or negative.</td>
</tr>
<tr>
<td>Antinuclear antibody</td>
<td>Target value ±2 dilutions or positive or negative.</td>
</tr>
<tr>
<td>Anti-streptolysin O</td>
<td>Target value ±2 dilution or positive or negative. Reactive or nonreactive.</td>
</tr>
<tr>
<td>Anti-Human Immuno-deficiency virus</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>Complement C3</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>Complement C4</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>Hepatitis (HBsAg, anti-HBc, HBeAg)</td>
<td>Target value ±3 SD. Reactive (positive) or non-reactive (negative).</td>
</tr>
<tr>
<td>IgA</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>IgE</td>
<td>Target value ±3 SD.</td>
</tr>
<tr>
<td>IgG</td>
<td>Target value ±25%.</td>
</tr>
<tr>
<td>IgM</td>
<td>Target value ±3 SD. Target value ±2 dilutions or positive or negative. Target value ±2 dilutions or positive or negative. Target value ±2 dilutions or positive or negative.</td>
</tr>
<tr>
<td>Infectious mononucleosis</td>
<td>Target value ±2 dilutions or positive or negative.</td>
</tr>
<tr>
<td>Rheumatoid factor</td>
<td>Target value ±2 dilutions or positive or negative.</td>
</tr>
<tr>
<td>Rubella</td>
<td>Target value ±2 dilutions or immune or nonimmune or positive or negative.</td>
</tr>
</tbody>
</table>

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

\[
\text{Analyte score for the testing event} = \frac{\text{Number of acceptable responses for the analyte} \times 100}{\text{Total number of challenges for the analyte}}
\]

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

\[
\text{Testing event score} = \frac{\text{Number of acceptable responses for all challenges} \times 100}{\text{Total number of all challenges}}
\]