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

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

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

§ 493.941 Hematology (including routine hematology and coagulation).

(a) Program content and frequency of challenge. To be approved for proficiency testing for hematology, a 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 values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS’ option, may be provided to HHS and or its designee for on-site testing.

(b) Challenges per testing event. The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

(1) Cell identification or white blood cell differential.
(2) Erythrocyte count
(3) Hematocrit (excluding spun microhematocrit)
(4) Hemoglobin
(5) Leukocyte count
(6) Platelet count
(7) Fibrinogen
(8) Partial thromboplastin time
(9) Prothrombin time

Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(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 responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory’s response 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 score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte 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 is determined using either fixed criteria based on the percentage difference from the target value 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>Cell identification</td>
<td>90% or greater consensus on identification.</td>
</tr>
<tr>
<td>White blood cell differential</td>
<td>Target ±6% based on the percentage of different types of white blood cells in the samples.</td>
</tr>
<tr>
<td>Erythrocyte count</td>
<td>Target ±6%.</td>
</tr>
<tr>
<td>Hematocrit (Excluding spun hematocrits)</td>
<td>Target ±7%.</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Target ±7%.</td>
</tr>
<tr>
<td>Leukocyte count</td>
<td>Target ±15%.</td>
</tr>
<tr>
<td>Platelet count</td>
<td>Target ±25%.</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>Target ±20%.</td>
</tr>
<tr>
<td>Partial thromboplastin time</td>
<td>Target ±15%.</td>
</tr>
<tr>
<td>Prothrombin time</td>
<td>Target ±15%.</td>
</tr>
</tbody>
</table>

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

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

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

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

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