## Crosswalk of Adopted Revision to Parentage / Identity Standards

Only those standards with proposed revisions are included here. Any Parentage / Identity standards not addressed here remain in effect.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paternity/Identity Standard 1 (PIT S1)</strong></td>
<td>An individual who can be qualified as an expert witness in a court shall be available to provide legal testimony related to the test results.</td>
<td>PIT S1 Standard deleted. This is not an American Blood Bank Association (AABB) requirement.</td>
<td></td>
</tr>
<tr>
<td><strong>Paternity/Identity Standard 32 (PIT S32)</strong></td>
<td>Only those autoradiographs and membranes where the control DNA and size marker patterns meet the laboratory's pre-established criteria for acceptance shall be analyzed.</td>
<td>PIT S32 standard deleted. Please refer to General Systems Quality Control Standards.</td>
<td></td>
</tr>
<tr>
<td><strong>Paternity/Identity Standard 41 (PIT S41)</strong></td>
<td>The laboratory shall maintain the capability to type for all HLA-A and HLA-B antigens, for which sera is readily available, that are officially recognized by the HLA Nomenclature Committee of WHO: the broad specificity or, where applicable, the split of the major antigens shall be identified.</td>
<td>PIT S41 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.</td>
<td></td>
</tr>
</tbody>
</table>
**Paternity/Identity Standard 42 (PIT S42)**

The laboratory shall validate the specificity of antisera using cells of known type; and,

a) specificity of sera obtained locally shall be validated using a cell panel from a minimum of 40 subjects from various ethnic groups, which includes cells with antigens to which common HLA antibodies are directed, cells possessing only one defined HLA antigen at a locus and additional cells as needed to identify an antibody with certainty;

b) specificity of individual sera obtained from commercial or other laboratory sources shall be verified using a method which includes a positive and negative control for each serum tested with each cell panel;

c) reactivity of each lot of commercial typing trays shall be validated by pre-test against at least five different cells representing major specificities, or by testing in parallel with previously validated trays; and,

d) typing sera reactions shall be recorded, reviewed by a supervisor, and shall be used to modify locally prepared typing trays and applied to all tray interpretations.

**Paternity/Identity Standard 43 (PIT S43)**

When typing trays are locally prepared, the laboratory shall maintain sera inventory records which document the source, bleeding date, identification number and volume remaining for each serum lot.

**PIT S42 Standard deleted.**

Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.

**PIT S43 Standard deleted.**

Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.
<table>
<thead>
<tr>
<th>Paternity/Identity Standard 44 (PIT S44)</th>
<th>Negative controls have predominately live cells and positive controls have predominately dead cells.</th>
<th>PIT S44 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.</th>
</tr>
</thead>
</table>
| Paternity/Identity Standard 45 (PIT S45) | A complement dependent lymphocytotoxic method shall be used for cell typing and shall incorporate controls; and,  
  a)—each typing tray shall minimally include one complement-dependent positive serum control known to react with all cells, and one negative serum (or serum pool) control known to lack HLA antibody; and,  
  b)—cell viability in the negative control at the end of incubation shall be that value established by the laboratory to be sufficient to permit accurate interpretation of results. | PIT S45 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards. |
| Paternity/Identity Standard 46 (PIT S46) | Each specimen shall be tested by plating on two separate trays or tray sets, each containing a minimum of one monospecific or two multispecific sera defining each HLA-A and HLA-B locus tested. The sera defining a particular specificity should be from two different donors. | PIT S46 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards. |
| Paternity/Identity Standard 47 (PIT S47) | An established scoring system shall be used for the assignment of HLA antigens; testing personnel shall be trained in the use of the scoring system, and such training shall be documented. | PIT S47 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards. |
## Crosswalk of Adopted Revision to Parentage / Identity Standards

<table>
<thead>
<tr>
<th>Standard / Revision</th>
<th>Description</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Paternity/Identity Standard 48 (PIT S48)</strong></td>
<td>At least once every month, the ability of testing personnel to reproduce results shall be assessed, using a previously tested specimen as an unknown. Records of the results for each individual shall include the review date and specimen identification and shall be reviewed and approved by a supervisor.</td>
<td>Approval should be documented on the record. PIT S48 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.</td>
</tr>
<tr>
<td><strong>Paternity/Identity Standard 49 (PIT S49)</strong></td>
<td>Reports shall use terminology for HLA antigens which conforms to the latest report of the HLA Nomenclature Committee (WHO).</td>
<td>PIT S49 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.</td>
</tr>
</tbody>
</table>
| **Paternity/Identity Standard 50 (PIT S50)** | The SOPM shall contain:  
  a) the protocols for preparation and/or selection of typing reagents, whether locally or commercially prepared, and verification of reactivity;  
  b) if the laboratory uses locally prepared cell panels, a list of individuals for fresh panel bleeding;  
  c) the protocol for the preparation of lymphocytes;  
  d) the scoring system protocol used for antigen assignment, including, where applicable, literature references and/or instrument calibration documentation; policy for antigen redefinition and retyping, including, where applicable, the updating of results and issuance of amended reports; and,  
  e) the policy for remediation for those individuals not meeting the laboratory’s established level of performance for reproducibility of test results. | See Operating Procedures and Compliance Standards for additional SOPM requirements. PIT S50 Standard deleted. Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards. |
<table>
<thead>
<tr>
<th><strong>Paternity/Identity Standard 51 (PIT S51)</strong></th>
<th><strong>Performance in the cell exchange program should be at a satisfactory level such that the laboratory is able to identify either the broad specificity or, where applicable, the split of any major antigens.</strong></th>
<th><strong>PIT S51 Standard deleted.</strong> Laboratories using HLA-typing for parentage testing must comply with Histocompatibility standards.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The laboratory’s quality control program shall include participation in at least one national or regional cell exchange program, including the Southeast Organ Procurement Foundation (SEOPF), the International Cell Exchange sponsored by the UCLA Tissue Typing Laboratory, the College of American Pathologists and the American Society of Histocompatibility and Immunogenetics (ASHI/CAP), or other as approved by the Department.</td>
<td>If performance in cell exchange is poor, the laboratory should identify the reason for poor performance, resolve the problem, and document action taken.</td>
<td></td>
</tr>
</tbody>
</table>

June 2014
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The report shall minimally contain the following information:</td>
<td>The report shall minimally contain the following information:</td>
</tr>
<tr>
<td>a) the date(s) the samples were collected;</td>
<td>a) the date(s) the samples were collected;</td>
</tr>
<tr>
<td>b) the name of each individual tested and the relationship to the child;</td>
<td>b) the name of each individual tested and the relationship to the child;</td>
</tr>
<tr>
<td>c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;</td>
<td>c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;</td>
</tr>
<tr>
<td>d) the phenotypes established for each individual in each genetic marker system examined;</td>
<td>d) the phenotypes established for each individual in each genetic marker system examined;</td>
</tr>
<tr>
<td>e) a statement as to whether or not the alleged father can be excluded;</td>
<td>e) a statement as to whether or not the alleged father can be excluded;</td>
</tr>
<tr>
<td>f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;</td>
<td>f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;</td>
</tr>
<tr>
<td>g) if there is a failure to exclude, the report shall include:</td>
<td>g) if there is a failure to exclude, the report shall include:</td>
</tr>
<tr>
<td>i. the paternity index for each genetic marker system reported;</td>
<td>i. the paternity index for each genetic marker system reported;</td>
</tr>
<tr>
<td>ii. the combined paternity index; and,</td>
<td>ii. the combined paternity index; and,</td>
</tr>
<tr>
<td>iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;</td>
<td>iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;</td>
</tr>
<tr>
<td>h) an explanation of the nature of the problem, if the results are inconclusive; and,</td>
<td>h) an explanation of the nature of the problem, if the results are inconclusive; and,</td>
</tr>
<tr>
<td>i) the signature of the laboratory director.</td>
<td>i) the signature of the qualified person who reviewed, approved, and interpreted the test results.</td>
</tr>
</tbody>
</table>

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the laboratory director.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the qualified person who reviewed, approved, and interpreted the test results.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the laboratory director.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the qualified person who reviewed, approved, and interpreted the test results.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the laboratory director.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the qualified person who reviewed, approved, and interpreted the test results.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the laboratory director.

- **Paternity/Identity Standard 66 (PIT S66)**

  The report shall minimally contain the following information:

  a) the date(s) the samples were collected;
  b) the name of each individual tested and the relationship to the child;
  c) the racial origin(s) assigned by the laboratory to the mother and alleged father for the purpose of calculation;
  d) the phenotypes established for each individual in each genetic marker system examined;
  e) a statement as to whether or not the alleged father can be excluded;
  f) if an opinion of nonpaternity is rendered, the basis for the opinion shall be provided;
  g) if there is a failure to exclude, the report shall include:
    i. the paternity index for each genetic marker system reported;
    ii. the combined paternity index; and,
    iii. the probability of paternity, including the prior probability used to calculate the probability of paternity;
  h) an explanation of the nature of the problem, if the results are inconclusive; and,
  i) the signature of the qualified person who reviewed, approved, and interpreted the test results.