

## Proposed Parentage/Identity Standards – Comments and Responses

Proposed Standards were made available to New York State permitted laboratories and laboratories in application for a permit on March 4<sup>th</sup>, 2020. The announcement was by e-mail to the facility and laboratory contact person's e-mail address and the Proposed Standards were posted to the CLEP website.

The comment period ended June 15<sup>th</sup>, 2020. Comments received from any regulated parties and responses are shown here.

Standards will be adopted July 13<sup>th</sup>, 2020, with an effective date of August 1<sup>st</sup>, 2020.

### Parentage/Identity Testing

<b>Parentage/Identity Testing</b>	
<b>Proposed Standard</b>	<b>Proposed Guidance</b>
<b>Parentage/Identity Testing Standard of Practice 1 (PIT S1): Specimen Testing</b>  Testing of all specimens in a paternity/identity case <b>must should</b> be performed in the same laboratory and using the same methods. <b>If extenuating circumstances require outsourcing of a portion of the test to another facility, the reporting laboratory must perform a review of all test results prior to reporting and note any other testing facilities in the report.</b>	

### Parentage/Identity Testing Standard of Practice 1 (PIT S1): Specimen Testing

#### **COMMENT:**

According to AABB:

**4.2.3.1** When another laboratory provides genetic test results, that laboratory shall be accredited by the AABB or other equivalent accrediting body for that activity. Reference Standard 6.3A, Requirements for Test Reports, #A7 applies.

**Reference Standard 6.3A. Requirements for Test Reports Chain of Custody Reports**

**A. Identifiers**, 7 The identity of any other laboratory that provided genetic test results used in the report and all portion(s) of the report for which that laboratory was responsible.

**Guidance**

When relationship testing procedures or other services required by these RT Standards are outsourced, the laboratory is expected to have a copy of the current accreditation certificate of the laboratory to which relationship testing procedures or other services are outsourced. Occasionally the laboratory may use results from other laboratories because of extenuating circumstances (e.g., deceased alleged father) or by law. These non-routine uses of outside reports would not require obtaining an accreditation certificate; however, if the laboratory knows the outside results do not meet accreditation standards, it should be noted in the report submitted to the client.

**RESPONSE:**

Based on the comment received, the standard has been revised to indicate that If extenuating circumstances require outsourcing of a portion of the test to another facility, the reporting laboratory must perform a review of all test results prior to reporting and note any other testing facilities in the report.