4. SUPPLIERS AND CUSTOMERS

4.0 Suppliers and Customers

The laboratory shall have policies, processes, and procedures to verify that critical services and supplies (including equipment, reagents, and materials) and samples obtained from outside sources consistently meet specified requirements.

✎ **4.1 Supply Identification**

Requirements and specifications for critical supplies and services shall be identified.

✎ **4.2 Supplier Qualification**

The laboratory director or a designated representative shall evaluate and participate in the selection of suppliers before acceptance of an agreement.

4.2.1 The laboratory director or a designated representative shall qualify suppliers based on their ability to meet specified supply or service requirements before acceptance of an agreement.

4.2.2 The laboratory director or a designated representative shall participate in the ongoing evaluation of suppliers.

4.2.3 Laboratory testing and other services required by these *RT Standards* shall be performed in a laboratory accredited by either the AABB or other, equivalent, accrediting body.

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.

4.3 Agreements

Agreements, or changes to those agreements, to obtain or provide materials, relationship test reports, and relationship testing services shall define supplier and customer expectations and shall reflect agreement.

4.3.1 Agreement Review

The laboratory director or designated representative shall verify that the identified requirements are 4.3.2

4.3.2 Agreements shall be reviewed at defined intervals, and revised as needed.

4.3.3 There shall be written agreements between laboratories and third-party administrators that define the following:

1. Collection requirements.
2. Responsibility for the testing process.
3. Reporting of test results.
4. Appropriate marketing materials and claims.
5. Use of the laboratory's name and accreditation status.
6. Unless accredited for collection or verification activities by AABB, third-party administrators are prohibited from initiating cases for United States of America immigration, visa, passport, and citizenship testing.

Standards 5.2.3.5, 6.4.4, and 6.4.5 apply.

4.4 Supplier Evaluation

The laboratory director or a designated representative shall evaluate at defined intervals whether suppliers have met agreed-upon requirements and take appropriate follow-up action.

4.4.1 The laboratory shall have a process to review promotional materials of contracted third party administrators at defined intervals to ensure that the information contained therein comply with these *RT Standards*.

4.4.1.1 When a supplier fails to meet specified requirements, the laboratory director or a designated representative shall take appropriate action and report it to the facility's purchasing authority. Standard 7.0 applies.

4.5 Receipt, Inspection, and Testing of Incoming Critical Supplies and Samples

Incoming reagents, samples, materials, equipment, and products shall be inspected and tested before reporting of results. The laboratory shall ensure that:

1. Each lot shall be tested.
2. Each shipment, regardless of lot, shall be tested.
3. Each lot within a shipment shall be tested.

4.5.1 Criteria for acceptance and rejection of the inspection and testing shall be established.

4.6 Management of Supplies and Materials

The laboratory director or a designated representative shall ensure that the laboratory has processes that address the availability, control, storage, handling, and transportation of critical supplies and reagents.

4.7 Traceability

Critical supplies and samples shall be traceable to the finished product and/or service.

4.7.1 The facility shall have policies, processes, and procedures to evaluate and respond to possible altered or fabricated documents.