QUALITY MANAGEMENT - IVM

ANP.57150 IVM Quality Manual **Phase I**

The quality manual defines adequate processes to monitor IVM services.

NOTE: The specific components of the quality management system are left to the discretion of the IVM service. Examples include monitoring the quality of clinical information provided to ensure it is adequate for the intended use of the system, and monitoring disparities between initial IVM dataset interpretation and final pathology diagnosis.

ANP.57200 IVM Appropriate Use **Phase I**

The laboratory ensures that the systems used for IVM are appropriate for the intended clinical use.

NOTE: The procedure manual must identify the appropriate use cases for IVM.

ANP.57250 System Validation - IVM **Phase I**

The IVM service validates IVM technology before it is used for the intended diagnostic purpose(s).

NOTE: The specific components of the validation study are left to the discretion of the IVM service. However, studies should be performed using an adequate number of cases, data should be evaluated, and a summary statement provided prior to implementation. Records of how discordant data or unacceptable variations from the expected were resolved are required.

As general guiding principles, the validation process should:

- *Closely emulate the real-world clinical environment and involve tissue types and clinical settings relevant to the intended use(s)*
- *Be carried out by or under the supervision of a physician(s) adequately trained to use the IVM system*
- *Encompass the entire IVM system, with reevaluation if a significant change is made to a previously validated system.*

Evidence of Compliance:

✓ Records of completed validation study with supporting validation data, review and approval

ANP.57300 User Training - IVM **Phase I**

There are training records for all users of the IVM system.

NOTE: Users of the IVM system include individuals responsible for IVM dataset interpretation. Training may be a coordinated process between a clinical department and the laboratory, depending on the individual needs of the organization. Training records may be part of the credentialing process at a hospital or other health care facility or may be part of the pathology department's records. Because the field is rapidly evolving, consideration should be given to continuous learning opportunities.

Evidence of Compliance:

✓ Records for training of personnel on the use of the IVM system for diagnostic purposes

ANP.57350 Function Checks - IVM **Phase II**