Houston Forensic Science Center

2022 - 17025T - Reassessment

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Data collected on 2022-08-08

ANSI National Accreditation Board

United States

Description

This assessment report summarizes the outcome of the recent accreditation activity. A separate document, the assessment plan, provides information on the type of activity (*e.g.,* reassessment, surveillance activity, scope extension), the date(s) of the activity, the assessment team members, the requirement documents and the scope by discipline that was assessed for each location. The assessment plan, together with this report, provides a complete picture of the accreditation activity.

The ANSI National Accreditation Board (ANAB) evaluated the competence of the forensic service provider and conformance with all applicable accreditation requirements for the scope of accreditation listed in the assessment plan. Objective evidence of implementation was assessed. The results of an assessment activity are based on a sample of records, locations, and personnel that were available at the time of the activity. Witnessing is an additional technique used in on-site activities.

REQUIREMENTS:

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories & ANAB ISO/IEC 17025:2017 Forensic Science Testing and Calibration Laboratories Accreditation Requirements (AR 3125) evaluated over the accreditation cycle are summarized in the following broad categories:

General requirements related to the forensic service provider's commitment to impartiality and confidentiality in its activities.

Structural requirements related to the range of activities, management structure, the authority, roles and responsibilities of personnel. Documented procedures which ensure a consistent application of activities and the validity of results.

Resource requirements related to the impartiality of personnel. Requirements for a training program, competency testing, authorizations and ongoing monitoring to ensure the competence of personnel. Facility and security suitability for activities. Records and procedures for equipment to ensure proper functioning and where applicable, establishment of metrological traceability. Requirements for externally provided products and services.

Process requirements related to the handling of test and calibration items in a manner to maintain the integrity of the item. Requirements for chain-of-custody of items to be tested and appropriate methods and procedures. Ensuring the required performance of the methods along with monitoring the validity of the results. Requirements to ensure results are supported by sufficient technical records and are reported accurately, clearly, unambiguously and objectively. Procedures for nonconforming work and a documented process for handling complaints. Requirements related to the laboratory information management system protection and integrity of data and information.

Management system requirements related to policies and objectives appropriate for the scope of activities. Requirements to control internal and external documents and records. Requirements to address risks and opportunities and timely, well-documented corrective actions. Requirements for an internal audit program and management reviews.

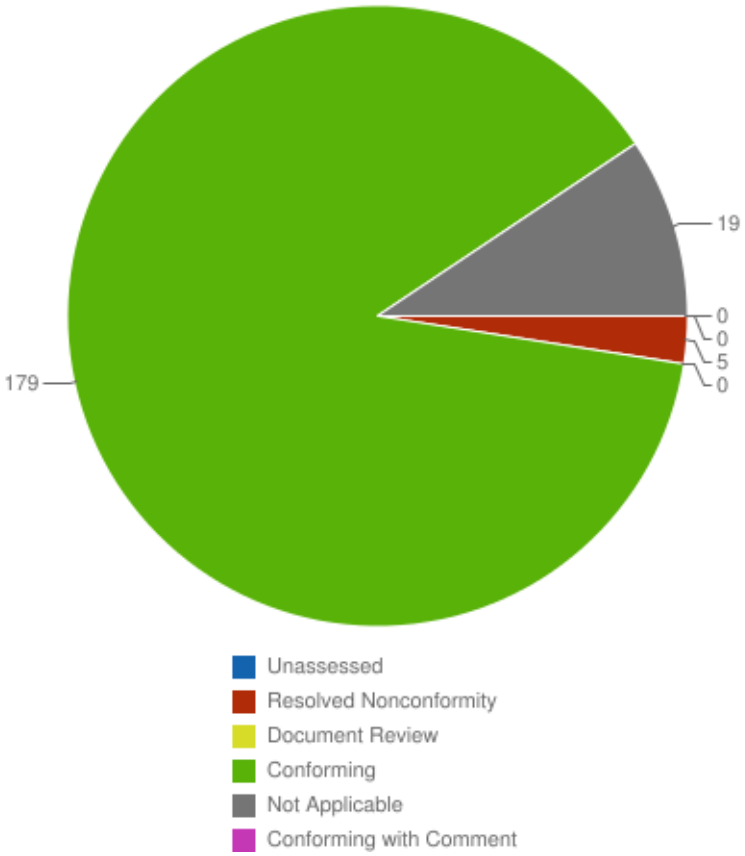
The accreditation activity also evaluates forensic science provider’s conformance with their own management system requirements.

ASSESSMENT RESULT:

Based on the assessment techniques and sampling reviewed during the assessment activity, the assessment team found that the forensic service provider demonstrated competence to operate a management system that fulfills all applicable accreditation requirements, including those specified within their management system.

Any comments (opportunities for improvement) or nonconformities identified during this assessment activity are noted below. All nonconformities will be resolved prior to an accreditation decision by ANAB and a summary provided in a subsequent assessment activity report.

Summary of Comments



Audit Comments

6.4 Equipment

6.4.4 ISO/IEC 17025:2017

Resolved Nonconformity

Requirement

Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service?

Nonconformity Resolution Workflow

Forensic Biology internal software validations, Exponent Tool excel worksheet revision 9/17/20, GlobalFiler Manual Amplification excel worksheet revision 3/4/21, Quant Trio excel worksheet revision 5/19/21, Quant Trio excel worksheet revision 11/22/21, does not include the determination of which studies will and will not be conducted as required by the QAS. (Quality Assurance Standard 8.8.a)

Corrective Action Closure Note: An evaluation of the nonconformity to determine the extent and cause were conducted. Root cause determined the laboratory had discussions regarding DNA validation studies that would or would not be performed but failed to document. A review of validation studies performed was conducted by the technical leader to determine if additional studies were needed. Memo dated October 3, 2022 documented the review and determined no additional studies were needed and no impact to casework. A Qualtrax validation plan workflow was created to document the evaluation of validations and determination of which studies would be conducted for new software or new modules of existing software. Reviewed Qualtrax validation plan workflow. This nonconformity has been resolved.

7.2.2 Validation of methods

7.2.2.1 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

Does the laboratory validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified? Is the validation as extensive as is necessary to meet the needs of the given application or field of application?

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:
a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.

Nonconformity Resolution Workflow

Forensic Biology internal software validations do not contain the required studies, Regression Testing- for GlobalFiler Manual Amplification Excel worksheet revision 3/4/21, Quant Trio excel worksheet revision 5/19/21, Quant Trio excel worksheet revision 11/22/21; Sensitivity studies or Specificity studies for GlobalFiler Manual Amplification excel worksheet revision 3/4/21, Quant Trio excel worksheet revision 5/19/21, Quant Trio excel worksheet revision 11/22/21, as required by QAS for analysis and interpretation software and statistical calculation software. (Quality Assurance Standards 8.1, 8.8, 8.8.3.2, 8.8.3.2.c, 8.8.3.2.e, 8.8.3.2.f, 8.8.3.3, 8.8.3.3.c).

Corrective Action Closure Note: An evaluation of the nonconformity to determine the extent and cause were conducted. Root cause determined the Biology section's functional study extended beyond solely the modifications made but rather function tested the workbooks as a whole, regression testing was inherently performed but not documented as such. Sensitivity and specificity studies was determined to be unnecessary by the technical leader but not documented. A review of validation studies performed was conducted by the technical leader to determine if additional studies were needed. Memo dated October 3, 2022 documented the review and determined no additional studies were needed, no impact to casework and sensitivity/specificity studies not needed. A Qualtrax validation plan workflow was created to document the evaluation of validations and determination of which studies would be conducted for new software or new modules of existing software. Reviewed Qualtrax validation plan workflow. This nonconformity has been resolved.

7.2.2.2 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

When changes are made to a validated method, is the influence of such changes determined and where they are found to affect the original validation, is a new method validation performed?

ANAB NOTE Changes to associated data analysis and interpretation are considered changes to a validated method.

Nonconformity Resolution Workflow

Forensic Biology internal software validations did not determine if the modifications result in major or minor revisions as required by the QAS for JusticeTrax LIMS Upgrade, Exponent Tool excel worksheet and Quant Trio excel worksheet. (Quality Assurance Standard 8.8.3)

Corrective Action Closure Note: An evaluation of the nonconformity to determine the extent and cause were conducted. Root cause determined the laboratory had discussions regarding whether the modifications were a major or minor revision but failed to document. A review of validation studies performed was conducted by the technical leader to determine if additional studies were needed. Memo dated October 3, 2022 documented the review and determined no additional studies were needed, no impact to casework and that software modifications for JusticeTrax LIMS Upgrade, Exponent Tool excel worksheet and Quant Trio excel worksheet were minor revisions. A Qualtrax validation plan workflow was created to document the evaluation of validations and determination of which studies would be conducted for new software or new modules of existing software. Reviewed Qualtrax validation plan workflow. This nonconformity has been resolved.

7.2.2.4 ISO/IEC 17025:2017 — Resolved Nonconformity

Requirement

Does the laboratory retain the following records of validation:
a) the validation procedure used?
b) specification of the requirements?
c) determination of the performance characteristics of the method?

d) results obtained?
e) a statement on the validity of the method, detailing its fitness for the intended use?

Nonconformity Resolution Workflow

d) and e)- Forensic Biology internal software validations do not contain all the required studies as outlined by QAS nor contain a statement on the validity of the method and its fitness for the intended use.

Corrective Action Closure Note: An evaluation of the nonconformity to determine the extent and cause were conducted. Root cause determined the Biology section's functional study extended beyond solely the modifications made but rather function tested the workbooks as a whole, regression testing was inherently performed but not documented as such. Sensitivity and specificity studies was determined to be unnecessary by the technical leader but not documented. A review of validation studies performed was conducted by the technical leader to determine if additional studies were needed. Memo dated October 3, 2022 documented the review and determined no additional studies were needed, no impact to casework and sensitivity/specificity studies not needed. A Qualtrax validation plan workflow was created to document the evaluation of validations and determination of which studies would be conducted for new software or new modules of existing software. Reviewed Qualtrax validation plan workflow. The documented approval of the Excel- based workbooks in Qualtrax, signified the technical leader's acknowledgement and approval that all required validations studies were performed. This also served as indication that the Excel-based workbooks were fit for the intended use. Excel workbook approvals from Qualtrax reviewed. This nonconformity has been resolved.

7.8.1 General

7.8.1.2.2 ANAB Accreditation Requirement — Resolved Nonconformity

Requirement

Is there a procedure for reporting of results that:
a) identifies what will be reported for all items received, including items on which no work was performed, items collected or created and preserved for future testing, and for partial work performed?
b) requires qualifying the significance of associations in the report whether by a statistic or a qualitative statement?
c) requires communicating the reason(s) in the report when the reported results are inconclusive? and
d) requires reporting of the initial database entry (e.g., DNA profiles, friction ridge, ballistics, biometrics)?

ANAB NOTE b) Associations for multiple results may be qualified by a single statistic or qualitative statement if the statistics are identical or, where applicable, meet or exceed a defined minimum threshold.

Nonconformity Resolution Workflow

b) In the Firearms discipline the significance of associations are not qualified in the report whether by a statistic or a qualitative statement.

Corrective Action Closure Note: An evaluation of the nonconformity to determine the extent and cause were conducted. Root cause determined the laboratory misinterpreted the requirement. Firearms reports included a hyperlink to a "Range of Conclusions" document which provided explanations of an identification (with a qualitative statement), exclusion, or inconclusive results. However, the hyperlink does not bring the user directly to the "Range of Conclusions" document. The Firearms section revised their report template to include the "Range of Conclusions" at the end of the Firearms reports. The Firearms section "Range of Conclusions" document was revised effective 100322 to provide a broader definition of an inconclusive conclusion. Firearms Section SOP effective 100322 reviewed. Firearms Section Range of Conclusions Document effective 100322 reviewed. The following types of Firearms reports reviewed: Inconclusive, identification and elimination. This nonconformity has been resolved.

Nonconformity Resolution Workflow

c) In the Firearms discipline the reason is not communicated in the report when the reported results are inconclusive.

Corrective Action Closure Note: An evaluation of the nonconformity to determine the extent and cause were conducted. Root cause determined the laboratory misinterpreted the requirement. The explanation of "inconclusive" that is listed in the "Range of Conclusions" document provides three distinct reasons for an examiner to render an inconclusive result. However, this distinction is not delineated for each specific comparison on the Firearms report. The Firearms section revised their report template to include the "Range of Conclusions" at the end of the Firearms reports. The Firearms section "Range of Conclusions" document was revised effective 100322 to provide a broader definition of an inconclusive conclusion. Firearms Section SOP effective 100322 reviewed. Firearms Section Range of Conclusions Document effective 100322 reviewed. The following types of Firearms reports reviewed: Inconclusive, identification and elimination. This nonconformity has been resolved.