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Alternative Performance Assessment

Proficiency testing (PT) is the determination of laboratory testing performance by means of interlaboratory comparisons. The CAP Laboratory Accreditation Program (LAP) requires enrollment in PT for many tests/activities/analytes (waived, non-waived, regulated, and non-regulated testing). Laboratories must enroll in a PT program from a CAP-accepted PT provider for required tests/activities/analytes.

Alternative performance assessment (APA) is a system for determining the reliability of tests for which PT is either not required or not available and for in vivo testing (e.g., bleeding time). An APA is required at least semi-annually. The following toolbox reflects options available and best practices for appropriate APA.

Note: International laboratories are required to enroll in CAP PT for all Test/Activities if a CAP PT program is available.

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Options for Alternative Performance Assessment

APA Procedure	Description	Advantages/Disadvantages
External PT program	✓ Enrollment in a PT program for a test/analyte/activity that does not require PT enrollment per CAP accreditation requirements. PT provider may or may not be CAP-accepted; and PT program may be graded, ungraded or educational *Note: International laboratories are required to enroll in CAP PT for all Test/Activities if a CAP PT program is available.*	✓ Commercial PT may allow comparison to a larger external peer group ✓ Better measure of accuracy relative to similar technology/testing, especially for graded PT program ✓ More standardized approach to assessment, usually within defined evaluation criteria ✓ PT may be ungraded due to: • Intended as educational challenge • Lack of participant or referee consensus • Small number of laboratories reporting (<10 quantitative or <5 qualitative) • If PT program is ungraded, laboratory must have policy/procedure for grading itself. Even ungraded, external PT often provides more information on test performance than other options for APA

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Options for Alternative Performance Assessment

APA Procedure	Description	Advantages/Disadvantages
Split-sample analysis	✓ External split-sample analysis: reference laboratory or other laboratory by a different method ✓ Internal split-sample analysis: previously assayed materials (audit-sample procedure) or different established in-house method ✓ For either external or internal split sample analysis, acceptability criteria must be defined in policy/procedure and results must be evaluated against defined acceptability criteria Qualitative testing: ✓ Recommended minimum number of samples is three, include at least one positive and one negative whenever possible Quantitative split-sample testing: ✓ 3 is the recommended minimum number samples. If only 2 of 3 match, the sample size should be increased to 6 • 5 of the 6 must match to be confident that results acceptable	✓ Best limited to tests for which other APA options are not feasible. External split sample analysis preferred over internal split-sample (different in-house method) or audit-sample (see below) ✓ Audit-sample procedure: • Can be used for stable analytes • Aliquots of stored patient sample • Analyzed periodically over time • Assesses reproducibility and stability of calibration • Does not assess trueness, only changes in test/system performance over time ✓ Split-sample analysis • Avoids matrix effects, probes preanalytic error • Storage, processing may still differ from routine patient testing

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Options for Alternative Performance Assessment

APA Procedure	Description	Advantages/Disadvantages
Clinical validation by chart review	✓ Clinical correlation studies	✓ Best limited to tests for which other APA options are not feasible • Can be used when the presence of the disorder can be independently determined at a reasonable point in time after testing ✓ Limit applications as confounded by: • Imperfect correlation of clinical events to laboratory results • Test referral bias • Disease classification bias
Direct observation of technique-dependent tests	✓ Observed by senior analyst or supervisor ✓ Checklist with factors to be observed capturing all elements of the procedure	✓ Best limited to tests for which other APA options are not feasible, such as in vivo testing (e.g., bleeding time)
Other methods suggested by guidelines from Clinical and Laboratory Standards Institute	✓ Analysis of manufacturer's product calibrator or control material ✓ Analysis of interlaboratory quality control data ✓ Analysis of patient data (averages of patient data and reference intervals)	✓ Best limited to tests for which other APA options are not available, calibrator and control material provide little evidence of trueness or accuracy

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Options for Alternative Performance Assessment

APA Procedure	Description	Advantages/Disadvantages
Sample Exchange Registry	✓ Internet-based service ✓ Connects laboratories performing rare analyte testing where no formal PT is available ✓ When ≥3 laboratories are identified as testing for the same analyte, CAP will facilitate the sample exchange ✓ CAP will distribute the samples to participating laboratories ✓ Laboratories will test the samples and send their results to CAP ✓ Data will be anonymized, and each individual laboratory will receive its own results along with an anonymous summary report of all the participants ✓ Immunohistochemistry (IHC) • CAP program for exchanging materials used for validation • Laboratories performing IHC testing must validate their assay prior to use • • Identify the markers your laboratory needs validating ✓ CAP will facilitate the exchange of slides—15 unstained slides from at least one positive and one negative case for each marker	✓ Can participate in this service at any time ✓ May be a good option for newer or complex testing that does not yet have formal PT program available

Alternative Performance Assessment Requirements

APA Components	Description
Procedure for APA	✓ Determine what analytes/tests require APA ✓ Determine what procedure will be used to assess analyte/tests that require APA ✓ (see Options for APA) ✓ Establish evaluation criteria/acceptability limits
Performance of APA	✓ At least semi-annually ✓ Test samples that span the analytical measurement range ✓ Use patient samples if not using an external PT program ✓ Test enough samples
Documentation of APA	✓ Document performance ✓ Evaluate for trends ✓ Corrective action for any unacceptable results ✓ Review by laboratory director or designee