











Accuracy monitoring ensures that tests tied to clinical guidelines are not only precise, but also correct. It has a huge impact on the cost and quality of patient care.



– **DAVID W. SECCOMBE** MD, PhD, FCAP Managing Director, CEQAL

INTRODUCTION



WSLH has partnered with CEQAL to offer laboratories the largest menu of accuracy-based programs anywhere in the world.

Proficiency testing serves as a valuable and efficient means to check the precision of a given method within a peer group. The samples have long shelf lives and many analytes can often be tested within a single sample. It is a requirement for lab accreditation and a worthwhile component of quality control.

One of the potential shortcomings, however, is that PT does not allow laboratories to compare results relative to a 'gold standard' or internationally credentialed reference method. In other words, PT can tell you whether or not a given method is reproducible, but it won't reveal if a calibration bias exists relative to a correct value from a reference method. Nor is it possible to know whether matrix effects are causing the sample to behave in a way that is inconsistent with an actual patient sample.

That's where accuracy monitoring can help supplement PT to help ensure the validity of key clinical tests. Accuracy-based programs are of particular importance for tests that are tied to evidence-based guidelines, where established cut points exist that drive medical decision-making. Being challenged at the appropriate levels and knowing with certainty that your results are not just consistent but correct is of the utmost importance to patient care.

WSLH is proud to be providing these innovative programs at a reduced cost to our members and we remain committed to the continual improvement of laboratory testing throughout the country.

Sincerely,

KRISTINE S. HANSBERY MBA, BS, MT (ASCP) Director, Laboratory Improvement Division, WSLH PT

Kristine Hansbery)

PT VS. ACCURACY

The table below highlights some of the key differences between proficiency testing and accuracy monitoring.

| | PROFICIENCY TESTING | ACCURACY MONITORING |
|---------------------------------------|---|---|
| Sample Commutability | Unknown, possible matrix effects | Commutable, 100% human material |
| Target Value Assignment | Group mean for a given analyzer, method, etc. | Reference method or gravimetric additions |
| Analyte Challenge Levels | Program dependent, highly variable | Clinically significant, tied to guidelines |
| Key Performance Metric | Standard deviation relative to peer group | Total error based on biological variation |
| Performance Reports | At the conclusion of each test event | Instantly displayed on Youden plots |
| Required by CLIA | Yes | Supplementary to PT |
| Reveals Potential Calibration Bias | N/A | Yes |
| Suitable for Harmonization | N/A | Yes |

SAMPLES

CEQAL's accuracy programs feature commutable samples with 100% human material sourced from inhouse clinics. Samples are screened for viruses at the donor level before being added to their pools. No preservatives or stabilizers are introduced at any point in the process. This ensures that the reference material is free of matrix effects that can contribute to error.

REFERENCE VALUES

CEQAL assigns reference values at clinically significant concentrations using either the internationally credentialed reference method for a given analyte (e.g. Lipids, HbA1c, Creatinine, Liver Function Tests) or through gravimetric additions of substances of known purity (e.g. Therapeutic Drugs, Urinary Albumin). These are the gold standards by which labs can reliably gauge accuracy.

SYSTEM & REPORTS

CEQAL has an intuitive online system for submitting results. Reports are generated in real time and data is displayed on Youden plots. This allows participants to quickly assess performance relative to reference values, as well as others in their network and region.



PROGRAM MENU

| HbA1c Monitoring | | \$215 Order # A1C2x3 |
|--|--|--|
| Format: 2 events x 3 samples (0.5 mL) | Sample matrix: 100% human whole blood | RV assignment: DCCT/IFCC reference method |
| Analytes: HbA1c | | |

| Creatinine/eGFR Monitoring | | \$435 Order # CRE2x3 |
|---|------------------------------------|---|
| Format: 2 events x 3 samples (1 mL) | Sample matrix: 100% human serum | RV assignment: ID-GCMS reference method |
| Analytes: Creatinine, eGFR (calculated) | | |

| Liver Function Monitoring | | \$435 Order # LFM2x3 |
|--|------------------------------------|---|
| Format: 2 events x 3 samples (0.7 mL) | Sample matrix: 100% human serum | RV assignment: IFCC primary reference methods, Doumas reference method |
| Analytes: ALKP, ALT, AST, GGT, Total Bilirubin | | |

| Lipids Monitoring | | \$435 Order # LIP2x3 |
|--|------------------------------------|--|
| Format: 2 events x 3 samples (2 mL) | Sample matrix: 100% human serum | RV assignment: Reference methods traceable to CDC, WHO/IFCC |
| | | |

Analytes: Apo A-1, Apo B, HDL, LDL (calc.), LDL (direct), Total Cholesterol, Lp(a)*, Triglycerides (total), Triglycerides (net)

*Target value assigned by all results median

| Total Cholesterol CDC Certification | | \$525 Order # TCC2x6 |
|--|------------------------------------|--|
| Format: 2 events x 6 samples (2 mL) | Sample matrix: 100% human serum | RV assignment: Reference method traceable to CDC |
| Analytes: Total Cholesterol | | |

| Neonatal Bilirubin Monitoring | | \$375 Order # NBM2x5 |
|---|---|--|
| Format: 2 events x 5 samples (0.5 mL) | Sample matrix: 100% human serum with human bilirubin conjugates | RV assignment: Doumas reference method |
| Analytes: Total Bilirubin, Direct Bilirubin | | |

| Therapeutic Drug Monitoring | | \$375 Order # TDM2x3 | |
|-----------------------------|--|------------------------------------|---|
| | Format: 2 events x 3 samples (2 mL) | Sample matrix: 100% human serum | RV assignment: Gravimetrically assigned |
| | | | |

Analytes: Acetaminophen, Amikacin, Caffeine, Carbamazepine, Digoxin, Ethanol, Gentamicin, Lithium, Methotrexate, Phenobarbital, Phenytoin, Primidone, Salicylates, Theophylline, Tobramycin, Valproic Acid, Vancomycin

| Urinary Albumin Monitoring | | \$395 Order # UAM2x3 |
|---|------------------------------------|---|
| Format: 2 events x 3 samples (0.5 mL) | Sample matrix: 100% human urine | RV assignment: Gravimetrically assigned |
| Analytes: Albumin, Albumin/Creatinine Ratio (ACR), Creatinine | | |

| Vitamin D Monitoring | | \$405 Order # VDM2x3 |
|--|------------------------------------|--|
| Format: 2 events x 3 samples (0.5 mL) | Sample matrix: 100% human serum | RV assignment: ID-HPLC-MS/MS Vitamin D reference method |
| Analytes: Vitamin D | | |

| Thyroid Monitoring | | \$415 Order # THY2x3 |
|--|------------------------------------|---|
| Format: 2 events x 3 samples (0.5 mL) | Sample matrix: 100% human serum | RV assignment: Dialysis / Mass spectrometry |
| Analytes: Free T3, Free T4 | | |

| Testosterone Monitoring | | \$435 Order # TES2x3 |
|--|------------------------------------|---|
| Format: 2 events x 3 samples (0.5 mL) | Sample matrix: 100% human serum | RV assignment: ID-HPLC-MS/MS Testosterone reference method |
| Analytes: Testosterone | | |

ABOUT CEQAL

CEQAL was established in 1988 as a reference method laboratory for the standardization of lipid testing in Canada. They are a member of the CDC's CRMLN (Cholesterol Reference Method Laboratory Network) and facilitate the lipids testing certification process for labs and instrument manufacturers globally. In addition to lipids, CEQAL operates several other reference methods and is recognized as an international authority on accuracy, standardization and harmonization.



To learn more, call 604.336.3695 or email info@ceqal.com

