

PROFICIENCY TESTING OR BIANNUAL VERIFICATION OF ACCURACY

Laboratories performing any of the following regulated, non-waived analytes must participate in an approved proficiency testing program according to the CLIA requirements [as specified in 42 CFR 493.801 - 493.959 (Subparts H and I)]. The minimum number of challenges is 5 samples per testing event, with 3 testing events per year.

REGULATED ANALYTES (Proficiency Testing is Required):

CHEMISTRY

ALT/GPT
Albumin
Alkaline phosphatase
Amylase
AST/GOT
Bilirubin, total (or neonatal)
Blood gas pO₂, pCO₂, pH
Calcium, total
Chloride
Cholesterol, total
HDL Cholesterol
Creatine kinase
Creatine kinase isoenzymes
Creatinine
Glucose
Iron, total
LDH
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

ENDOCRINOLOGY

Cortisol
Free Thyroxine
Serum Pregnancy (HCG)
(qualitative or quantitative)
T3 Uptake
Triiodothyronine
TSH
Thyroxine

TOXICOLOGY

Alcohol, blood
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium
Phenobarbital
Phenytoin
Primidone
Procainamide (and metabolite)
Quinidine
Tobramycin
Theophylline
Valproic Acid

HEMATOLOGY

Cell Identification
Auto or manual WBC differential
Erythrocyte Count (RBC)
Hematocrit (automated)
Hemoglobin
Leukocyte count (WBC)
Platelet Count
Fibrinogen
Partial thromboplastin time
Prothrombin time

IMMUNOHEMATOLOGY

ABO Group
D (Rh typing)
Antibody Detection
Compatibility testing
Antibody Identification

SYPHILIS SEROLOGY

RPR, VDRL, MHA-TP, etc.

IMMUNOLOGY

Alpha-1 antitrypsin
AFP (tumor marker)
Antinuclear antibody
ASO
HIV
Complement C3, C4
HBsAg, Anti-HBc, HBeAg
IgA, IgE, IgG, IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

BACTERIOLOGY

Cover the specialty according to the different types of testing performed

MYCOLOGY

Cover the specialty according to the different types of testing performed

PARASITOLOGY

Cover the specialty according to the different types of testing performed

VIROLOGY

Cover the specialty according to the different types of testing performed

MYCOBACTERIOLOGY

Cover the specialty according to the different types of testing performed

If a laboratory performs tests that are not included on the list of regulated analytes, they must have a system for verifying the accuracy of their test results at least twice per year (biannual verification of accuracy). The minimum number of challenges is 2 samples, 2 times per year.

COMMON NON-REGULATED ANALYTES:

Microscopic examinations (KOH preps, wet mounts, pinworm preps, urine sediment, nasal smear for granulocytes, post vasectomy, Fern test); CO₂; GGT; Phosphorus; PSA; *H. pylori* antibody; Urine colony counts only; Hemoglobin A1C (glycosylated hemoglobin); Reticulocyte counts.

(continued on back)

APPROVED PROFICIENCY TESTING PROVIDERS:

Accutest	(800) 356-6788	California Thoracic Society	(714) 730-1944
Amer. Acad. of Family Physicians	(800) 274-7911	College of American Pathologists	(800) 323-4040
Amer. Assoc. of Bioanalysts	(800) 234-5315	EXCEL (CAP)	(800) 323-4040
American Proficiency Institute	(800) 333-0958	WSLH	(800) 462-5261
ASIM Medical Lab Evaluation	(800) 338-2746		

SUGGESTIONS FOR BIENNIAL VERIFICATION OF ACCURACY

- Include blind samples with known values in patient test runs.
- Participate in an external assessment program.
- Send split samples to another lab and compare results.
- Split samples with another instrument or method and compare results.
- For microscopic examinations, have two analysts review and compare results.
- Obtain Kodachrome slides from reference lab.
- Use peer group review of cases at professional meetings.
- Correlate patient test results with clinical history, presentation.

BE SURE TO:

- Have a written policy describing how the accuracy of testing is verified.
- Include specimens that span the reportable range for quantitative tests and establish criteria for acceptable agreement.
- Include specimens that give positive and negative results/reactions for qualitative tests.
- Include a minimum of 2 samples, 2 times per year.
- Document results of all verification activities.
- Document all corrective actions taken, if problems are identified and verify the effectiveness of the corrective action.