



## Commissioner's Corner August 2023

**QUESTION:** Is there an actual number of required PT challenges per year, and does the number differ if an analyte is CMS-regulated or CMS-unregulated? Do I have to enroll in more than one external proficiency testing program?

**ANSWER:** ASHI Standard C.1 Enrollment, Testing and Evaluation of Samples addresses PT challenges. The ASHI ARB Operations Manual 2022 version, XIV. Proficiency Testing (PT) Requirements clarifies the number of PT surveys/challenges for CMS-regulated and CMS-unregulated analytes.

For CMS regulated analytes, PT must include 5 challenges 3 times per year. This means the number of samples tested per analyte is five per PT survey and the laboratory is required to perform three surveys in a year.

For unregulated CMS analytes (includes HLA typing, HLA antibody, and XM), the minimum number of PT survey/challenges is twice a year. The minimum sample number tested per analyte is one per PT survey. However, your state or institution may have a more stringent requirement. The laboratory is required to perform two surveys per year.

Most PT providers for unregulated CMS analytes send at minimum three samples per PT survey. Submitting only one sample result can become problematic if there is a miss (i.e., unsatisfactory/discrepant). Unsuccessful participation in a PT program is defined as unsatisfactory performance on 2 consecutive send-outs or unsatisfactory performance on 2 out of 3 send-outs.

As for enrollment in an external proficiency testing program, per ASHI standard C.1.1.1, the laboratory is required to “participate in at least one graded external proficiency testing program that is approved by CMS for CMS-regulated analytes tested in CLIA-certified laboratories, or approved by the ASHI Accreditation Review Board for non-regulated analytes.”