

BLOOD PRODUCT CELL COUNTING · PERFORMANCE PROGRAM

Transfusion-Related Cell Count Alternative Assessment (TRC AA)

A twice-yearly, peer-comparison performance program built by LifeSouth's Special Testing Laboratory for laboratories counting cells in blood products.

What is it?

The TRC AA is an alternative performance assessment established by the Special Testing Laboratory (STL) at LifeSouth Community Blood Centers in Gainesville, FL. A CAP Transfusion-Related Cell Count (TRC) survey exists, but it is not compatible with the methods the Sysmex XN-10 uses in its BB modes: the XN reports a **fluorescent platelet count**, not the **impedance count** the existing survey is built around. To close that gap, the STL designed a custom assessment program to support both our own laboratories and the broader blood banking community. Samples are run according to your facility's SOP using the **Sysmex XN-10 BB modes**.

Proficiency Testing vs. Alternative Assessment

"PT" and "AA" are often used loosely, but under CLIA they are distinct. Knowing which one applies determines what a program can and cannot do for your compliance.

Proficiency Testing (PT) is formal external quality assessment regulated under CLIA (42 CFR Part 493, Subpart H). It applies to the regulated analytes listed in Subpart I, is administered by a CMS-approved provider that ships blind samples and grades your results against a defined target, and reports performance to CMS. Repeated unsuccessful performance can carry regulatory consequences, up to loss of certification for that analyte.

Alternative Assessment (AA) applies when no compatible CMS-approved PT is available, whether none exists or the only survey does not match your method, as with the XN's fluorescent platelet count. For these tests, CLIA still requires the laboratory to verify accuracy at least twice per year (42 CFR 493.1236(c)(1)) and to document that verification (493.1236(d)). An AA supplies method-appropriate comparison samples and peer group data, but it is not graded by a CMS-approved provider.

	Proficiency Testing (PT)	Alternative Assessment (AA)
Regulatory basis	CLIA Subpart H; regulated analytes in Subpart I	CLIA 493.1236(c)(1): twice-yearly accuracy verification
Provider	CMS-approved PT program	Suitable materials/method; not CMS-approved
Grading	Graded and scored by the provider; reported to CMS	Facility evaluates and documents its own results
When it applies	Regulated analytes with a compatible CMS PT	Tests with no compatible CMS-approved PT

Where TRC AA fits: LifeSouth is not a CMS-approved PT provider. The TRC AA is an alternative assessment, not a true proficiency test. It gives you method-appropriate samples and peer group data twice a year to support your 493.1236(c) accuracy verification. It does not replace CMS-graded PT for regulated analytes, and it does not relieve your facility of evaluating and documenting your own acceptability.

Schedule & fee

- Shipped twice a year: **Spring** (March/April) and **Fall** (September/October).
- Materials ship on a **Tuesday** to arrive by **Wednesday** for testing.

\$300

PER SHIPMENT

\$600

PER YEAR

What's included

Each shipment contains **6 samples**, with both leukoreduced and non-leukoreduced residual WBC material:

- **4 platelet samples** — platelet count and residual WBC testing
- **2 RBC samples** — hematocrit and residual WBC testing

How results are submitted

- Each participating site receives a **unique participant ID** for result submission.
- Results are entered through our **online submission portal**, which streamlines data collection and lets us return summaries faster.

How results are summarized

- Summaries are returned **within one month** of the final submission date.
- A **group mean** is calculated for each platelet and RBC sample.
- Platelet count acceptability criterion: **±25%** of target value.
- Hematocrit acceptability criterion: **±4%** of target value.
- Residual WBC results are summarized by **intended result**: whether the sample was leukoreduced or non-leukoreduced.

Important: LifeSouth is not a CMS-approved PT provider. This program is an Alternative Assessment, not a true proficiency test. Each facility must analyze its own results for acceptability and document the outcome.

How to sign up

To participate or ask questions, email at:

TRCAA@lifesouth.org