If your laboratory has experienced a **PT Failure** on this event, please read the following:

The Laboratory Director and/or Technical Consultant must review and document their review of the enclosed Proficiency Testing results. ALL PT failures must be investigated. The results of the investigation and all remedial action must be documented. PT documentation must be maintained for a minimum of 2 years.

A PT failure occurs when the results reported by your laboratory do not fall within the acceptable range for that particular analyte. The acceptable range is calculated using the grading criteria established by CLIA and the percent consensus of participating laboratories. If total analyte consensus is >80% (95% for immunohematology), the analyte is graded.

Investigating PT failure: *(For internal laboratory use only. Do NOT submit this checklist to AAFP-PT.)*

Possible Cause for Failure	Investigation Checklist	Suggested Actions
Data Scanning or Transmission Error	☐ Do evaluation results match your copy of submitted results?	Submit a Request for Corrected Evaluation form to AAFP-PT
Clerical Error	☐ Wrong data entered? ☐ Numbers transposed? ☐ Wrong units reported? ☐ Results reported in wrong section of result form? ☐ Correct instrument/method code used?	AAFP-PT is unable to correct clerical errors made by the participating lab. Determine how the error occurred and develop an action plan to prevent future clerical errors with PT or patient samples.
Sample Handling	☐ Was kit received within 48 hours of shipping? ☐ Was kit refrigerated immediately upon arrival? ☐ Were contents of kit correct & in good condition? ☐ Was testing performed with 7-10 days of receipt? ☐ Was sample at room temperature when tested? ☐ Was sample mixed well before testing? ☐ Was sample diluted properly, if required? ☐ Were special handling instructions followed?	Note expected kit receipt dates on office master calendar. Train office staff on proper kit handling protocol. Develop a protocol for notifying laboratory personnel when a kit has arrived. AAFP-PT recommends completing testing with 7-10 days of receipt. Specimens should be at room temperature and well mixed before testing. Review test result booklet for special handling instructions, including dilution methods. Train personnel on accurate dilution techniques.

Possible Cause for Failure	Investigation Checklist	Suggested Actions
Testing Procedures	☐ Is a current copy of the manufacturer's package insert available? ☐ Have personnel been trained on the test procedure? ☐ Was manufacturer's current procedure followed? ☐ Does instrument manufacturer have any special instructions for testing PT samples? ☐ Were samples mixed up?	Contact manufacturer for current testing procedure, including any special techniques for testing PT samples. Train testing personnel and perform competency assessment. Develop a policy for periodic retraining & continuing education.
Instrument/Kit	☐ Was instrument recently calibrated or due for calibration? ☐ Was maintenance performed recently? ☐ Was a new lot # of reagent or calibrators recently introduced? ☐ Are reagents within expiration dates? ☐ Were kit components substituted from other kits? ☐ Were results within reported linearity for instrument? ☐ Does the sample demonstrate a "matrix effect"?	Consult instrument manufacturer for assistance in verifying instrument performance and establishing calibration & maintenance schedules. Develop an inventory system to eliminate expired reagents/kits. Never interchange kit components. Consult instrument manufacturer to determine if any known "matrix effects" exist with PT samples.
Quality Control	☐ Is QC within established range? ☐ Does QC demonstrate an even distribution (above/below) mean? ☐ Is there evidence of a shift, trend, or bias with QC results?	Review pages 15-17 of the AAFP-PT Handbook for information on QC shifts, trends, & bias. Consult instrument manufacturer for assistance on interpreting QC results.
Sample Problem	☐ Does a single sample fail for several analytes?	Possible sample problem, contact AAFP-PT.
Random Error	☐ Does a single sample fail for one analyte only? ☐ Have all other potential sources of error been ruled out?	Statistics indicate that 1 out of 20 results may fall outside of a specified limit. This should be documented as random error or normal statistical variation.