

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0675381	(X3) Date Survey Completed 05/16/2019
Name of Provider or Supplier Pittsburg Hospital, Llc	Street Address, City, State 2701 Us Hwy 271 North, Pittsburg, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing (PT) documentation for 2018 and 2019, the laboratory failed to test PT samples for manual cell counts on body fluids in the same manner as patient specimens. Findings: 1. API PT documentation for manual cell counts on body fluids for 2018 and 2019 revealed the following results: 3rd event 2018 Basophils Sample Reported Expected Score BFL-03 0 0-3 Acceptable BFL-04 0 0-3 Acceptable Eosinophils BFL-03 0 0-6 Acceptable BFL-04 0 0-6 Acceptable Lymphocytes BFL-03 66 0-35 Unacceptable BFL-04 0 0-36 Acceptable Monocytes BFL-03 0 0-21 Acceptable BFL-04 0 0-21 Acceptable Neutrophils BFL-03 34 62-100 Unacceptable BFL-04 0 60-100 Unacceptable 1st event 2019 Basophils Sample Reported Expected Score BFL-01 0 0-3 Acceptable Eosinophils BFL-01 0 0-7 Acceptable Lymphocytes BFL-01 56 0-36 Unacceptable Monocytes BFL-01 16 0-21 Acceptable Neutrophils BFL-01 28 60-100 Unacceptable 2. In an interview at the site on 05-15-2019, when questioned regarding unacceptable results for lymphocytes and neutrophils, technical consultant 1, who also serves as general supervisor 2 (CMS form 209) stated that the laboratory did not report patient results for differential counts on body fluids and that proficiency testing was being performed for educational use. .</p>

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

. Based on review of the laboratory procedure manual and staff interview, the laboratory had no written procedure for performance of D-dimer testing using the ACL TOP 300 hematology analyzer. Findings: 1. In the course of the survey, documentation regarding the laboratory procedure for performance of D-dimer testing was requested. Review of the laboratory procedure manual revealed no such procedure was included. 2. In an interview at the site on 05-16-2019, technical consultant 2 stated she was in the process of rewriting that policy. No written or electronic copy was available or could be offered during the survey. .

D5555

IMMUNOHEMATOLOGY

CFR(s): 493.1271(c)(f)

(c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

. Based on review of blood product storage temperature documentation, surveyor observation and staff interview, the laboratory failed to provide an audible alarm for monitoring of storage temperatures in the freezer used to store fresh frozen plasma (FFP). Findings: 1. Blood product storage temperature charts for 2017, 2018 and 2019 were reviewed. It was noted that no evidence of alarm checks appeared on charts for the freezer used to store FFP. 2. Visual inspection of the freezer revealed that no audible alarm system for temperature monitoring was installed. 3. In an interview at the site on 05-15-2019, technical consultant 2, who also serves as general supervisor 1, stated she was unaware of the requirement for an audible alarm on freezers used for blood product storage.