Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2117243	08/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Total Path Lab, Llc	5431 Barker Cyress Road Ste 1300, Houston, 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
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIAcertified and CLIA-exempt laboratories The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. Refer to D8103
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii)

Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and confirmed in interview, it was revealed the laboratory was not an active laboratory ready to perform non-waived histopathology testing. Findings were: 1. Review of the CMS116 revealed the laboratory would perform 55000 histopathology tests annually and the hours of operation were 9 am to 5 pm Monday through Friday. The laboratory certificate of registration was effective from 8/11/16 to 8/10/18. 2. An attempted tour of the facility on 08/06/18 at 1125 hours revealed the laboratory was locked. State agency surveyors requested for the laboratory representative from the 45D2115530 laboratory for entry to this laboratory. After she placed a few phone calls, she was given the door code and allowed state agency entry into the laboratory on 08/06/18 at 1320 hours. Surveyor observations of the laboratory space revealed no testing personnel nor any patient specimen for histopathology testing. 3. Random review of the laboratory records observed on a countertop in the "Frozen Sectioning area" revealed 2 of 2 patient pathology reports with no corresponding slides. Date accession number 8/22/16 TP16-00010 8/02/16 TP16-00009 Review of the TP16-00009 pathology report revealed handwritten notes on the report "Fax 844-681-2028"; "281-656-8734"; "CLIA #"; "move CLIA # to website"; "signature"; "make smaller font (7)." An interview with the laboratory representative on 08/06/18 at 1340 hours acknowledged that the above reports "looked like sample reports, not true patient reports." 4. Random sampling review of the laboratory maintenance and environmental logs available for review from 2016-2018 revealed documentation the laboratory had not monitored the room temperature nor had the testing personnel performed the required maintenance since the following corresponding dates. a. Antibody receipt log - last entry on 11/8/16 Antibody "PGP9. 5" b. Equipment Maintenance log - last entry on 4/2/18 with "NS" [not in use]; last entry with initials "DK" to indicate completed the maintenance on 2/5/18. c. Maintenance Record EZ Prep 1X - last entry on 5/12/16: prep date [preparation date] - lot ID F09610 d. Maintenance Record pH meter calibration - last entry on 11/7/16 e. Equipment Maintenance Log Microscope #3 - last entry on 2/28/18 with "NS" f. Equipment Maintenance Log Refrigerator - last entry on 3/2/18 5. Random review of available slides on a countertop by the "IHC [Immunohistochemistry] staining area" revealed 1 patient with various stained slides with Congo Red. SD16-0202917 S16. 1233A Review of the corresponding patient specimen report revealed a final report from another laboratory 45D2032918. 6. Review of the laboratory records revealed no documentation of education, training, or competency for any testing personnel. 36914 7. Direct observations made on August 6, 2018 at 13:30 hours in the laboratory revealed the following expired items: a. Giemsa Stain Kit (Lot 39179) Expiration date: October 2017 b. Buffer Solution - pH 7.00 (Lot 6GD380) Expiration Date: April 2018 Quantity of 1 bottle c. Buffer Solution - pH 4.00 (Lot 6GD622) Expiration Date: April 2018 Quantity of 1 bottle d. Buffer Solution - pH 10.00 (Lot 6GC610) Expiration Date: March 2018 Quantity of 1 bottle e. Nuclear Fast Red (Lot 16032406) Expiration Date: March 24, 2017 Quantity of 1 gallon f. Zamboni's Fixative (Lot 16102545) Expiration Date: August 25, 2017 Quantity of 3 bottles g. Hematoxylin (Lot 372519) Expiration Date: October 2017 Quantity of 3 gallons 8. An interview

	with the facility representative that provided access to the laboratory on August 6, 2018 at 13:40 hours in the laboratory confirmed the findings. She acknowledged that no patient testing had been performed.