Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660617	08/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Laboratories Inc	1111 W 34th Street Suite 100, Austin, 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	An on-site recertification survey was conducted on July 31, 2018 and August 1, 2018. Prior to the recertification survey, the ASCT survey team surveyed the laboratory for the specialty of Cytology. Findings can be found on survey event 088R11. At the time of the exit conference, the Laboratory Director and Laboratory Manager had responded to the findings of the ASCT team survey.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of Piccolo chemistry analyzer verification studies, laboratory procedures, and interview with facility personnel, the laboratory failed to retain records of the verification of patient reference (normal) ranges. The findings included: 1. Based on review of verification study documentation: "Instrument PICCOLO EXPRESS Test(s) COMPREHENSIVE METABOLIC PANEL This validation study has been reviewed and the performance of the method is considered acceptable for patient testing." This document was signed by the laboratory director on 7/11/11. 2. Review of the manufacturer instruction titled "VERIFICATION PROCEDURE', 100-7137 Rev. A, on page 1 of 3, states the following: "CMS (493.1253) Standard: Establishment and Verification of Performance Specifications states that the laboratory is responsible for verifying the performance specifications of each non-waived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results. The verification of method performance should provide evidence of accuracy, precision, and reportable range are adequate to meet the client's needs, as determined by the laboratory director and clinical consultant. A laboratory may use the manufacturer's performance guideline, but is responsible for verifying the

	manufacturers analytic claims before initiating patient testing. The laboratory may use the manufacturer's reference ranges provided it is appropriate for the laboratory's patient population. Refer to the Comprehensive Metabolic Panel Package Insert for reference values. Abaxis has developed an easy-to-use procedure to verify instrument and reagent performance based on testing and analyzing the panels for which you will be reporting results. Supplied for this procedure are: Nova-One Verification samples and Piccolo Comprehensive Metabolic Panel reagent discs. The procedure is completed over a period of time per Lab Consultant or Lab Director's instructions. The procedure will verify accuracy, precision, and reportable range. At the completion of the procedure, submit results to your Lab Consultant or Lab Director for analysis. The Lab Consultant or Lab Director will submit a report of the results for your records." 3. Based on review of the Piccolo Express Chemistry Analyzer Procedure (Effective 6/12/2018), the laboratory had defined reference ranges from another laboratory and was not using manufacturer provided reference ranges or ranges from published clinical literature. Example: Analyte: Albumin Manufacturer provided reference range: 3.3 - 5.5 mg/dL Reference range in use by the laboratory: Age: 0 Range: 3.5-5.2 mg/dL Age: 1M Range: 2.6-4.2 mg/dL Age: 5M Range: 2.8 - 4.4 mg /dL Age 6 Y Range: 3.0 - 4.8 mg/dL Age: 17Y Range: 3.6 -5.2 mg/dL Age: 150Y Range: 3.5 - 5.2 mg/dL 4. The surveyor and the laboratory manager reviewed the initial verification study from 2011 for the Piccolo chemistry analyzer and were unable to locate the verification of patient normal (reference) ranges. In an interview at 11:30 hours on August 1, 2018, the lab manager stated the study had been performed prior to her appointment of oversight and she was uncertain where the records of verification of patient normal ranges were stored, if not in the verification study binder.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control documentation, patient records, and interview with facility personnel, the laboratory failed to perform and document two levels of quality control on the Sure-Vue Mono Kit on June 29, 2018 for 1 of 1 patient specimen. The findings included: 1. Based on review of patient records, the laboratory performed a mononucleosis screen on patient SW0015240CZ795728 on June 29, 2018. The result was negative. 2. Based on a review of the Sure-Vue Mono Kit Patient Results and QC Worksheet for the month of June 2018, the laboratory failed to perform and document at least two levels of acceptable quality control on June 29, 2018. 3. In an interview at 15:15 hours on July 31, 2018 in the laboratory, the Laboratory Manager stated the testing individual had a high volume of patients on June 29, 2018 and had likely run the appropriate quality control, but had failed to document the results of the quality control on the appropriate worksheet.