Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0903424	04/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Pathology Laboratories, Inc	6818 Austin Center Blvd Ste 100 Rm 131, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, quality control records, testing logs, and interview, the laboratory failed to include the intended reactivity of the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics on their frozen section log used to document stain quality in histopathology for 23 of 23 months reviewed. Findings follow. A. Review of the Stat Lab Aqueous Eosin Y Procedure Instructions for Use, 01/17/2019, under Principle and Results stated, "Cytoplasm stains pale pink, collagen pink, muscle red, and red blood cells dark red." Review of the Thermo Scientific Richard-Allan Scientific Histology Signature Series Stains for Hematoxylin 2 Instructions for Use, revision 2015, stated, "nuclear chromatin" dyed "a distinct blue-purple color". B. Review of the Frozen Section Log from 03/23/2021 - 01/29/2023 showed the Stain Adequacy was deemed to be either good or poor with no definition of what "good" was. C. Interview with the Pathology Support Supervisor on April 6, 2023 at 1145 in the laboratory confirmed the staining

	characteristics were not included on the frozen section log or procedure. D. Review of the frozen section log showed from 03/23/2021 - 01/29/2023 11 patients were reported.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, pathology reports, slides, and interview, the laboratory failed to report the results of the frozen section interpretation for one of 10 histopathology test reports reviewed. Findings follow. A. Review of the Surgery Centers Frozen Section Room Procedure, AUS261356SOP effective 03/23/2023, under 4.0 Procedure stated, "...4.5 If a frozen is performed, the performing pathologist dissects the specimen for suitable sample and a piece(s) is placed on a chuck with frozen section medium and frozen in the cryostat. A representative section (cut at 4-6 microns unless otherwise indicated) is obtained and picked up on a slide labeled with assigned accession number 4.6 Slides (frozen section or touch prep) are stained with H&E (Hematoxylin & Eosin) stain 4.7 H&E Technique:... 4.8 Preparation is viewed under a microscope and a preliminary diagnosis is made 4.9 The performing pathologist renders the consultation and records it on the requisition or purpose-built consultation forms to include date and time of consultation as well as name of recipient of consultation..." B. Review of 10 histopathology cases showed the pathology report for case # BR0005720-2301, collected 01/25/2023, was missing the result of part A (Left breast) frozen section gross description and diagnosis. C. Review of the case slides showed the corresponding frozen section slides labeled FSA1 and FSA2. D. Interview with the Pathology Support Supervisor on April 6, 2023 at 1130 in the laboratory confirmed the results of the frozen section interpretation for part A was missing from the report.