Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2308658	04/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cpa-Lake Granbury Medical Center-Pathology	130 Paluxy Road, Granbury, 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 to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: I. Based on review of laboratory procedure, quality control (QC) records, patient test reports, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics and failed to document the intended reactivity (QC) for the Wright-Giemsa stain for peripheral blood smears for two of two patients in 2025 (January). Findings included: 1. Review of the laboratory's procedure titled "Wright-Giemsa (Bone Marrow Stain & Peripheral Smears)" stated: "RESULTS The differentiation of blood cell types. It is classically a mixture of eosin (red) and methylene blue dyes. It is used primarily to stain peripheral blood smears and bone marrow aspirates." The procedure failed to define the intended reactivity to ensure the predictable staining characteristics for the Wright-Giemsa stain used in the preparation of peripheral blood smears. 2. Review of QC records did NOT include for each day of use, documentation of the intended reactivity for the Wright-Giemsa stain peripheral smears performed in 2025. The following patients had peripheral smears on January 14, 2025, with NO documented QC being performed: Patient IDs: SUR25-000167, SUR25-000171 3. During an interview in the conference room on 04/30/2025 at 10:45 a.m., the Clinical Service Manager after a review of the records confirmed the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics and failed to document the intended reactivity

	(QC) for the Wright-Giemsa stain for peripheral blood smears for two of two patients in 2025 (January). II. Based on review of laboratory policy and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for four of four stains used in histopathology interpretations. Findings included: 1. Review of laboratory policies "IMMUNOHISTOCHEMISTRY ANTIBODY TITER WORKSHEET" for the MLH1, MLH2, MSH6 and PMS2 antibodies stated: "Stain intensity (0-4) & Background (low, med, high) Stain intensity 4+ Background 0 Staining Description: Nuclear The procedure failed to define the staining characteristics for intended reactivity for the MLH1, MLH2, MSH6 and PMS2 antibody stains used by the laboratory for histopathology interpretations. 2. During an interview in the conference room on 04/30/2025 at 10:57 a.m., the Clinical Service Manager after a review of the records confirmed the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for four of four stains used in histopathology interpretations.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to test and document MLH1, MSH2, MSH6 and PMS2 stains for positive or negative reactivity to ensure stain quality each day of use for one of one day in 2024 (random review October). Findings included: 1. Review of laboratory policies "IMMUNOHISTOCHEMISTRY ANTIBODY TITER WORKSHEET" for the MLH1, MLH2, MSH6 and PMS2 antibodies stated: "Stain intensity (0-4) & Background (low, med, high) Stain intensity 4+ Background 0 Staining Description: Nuclear The procedure failed to define the staining characteristics for intended reactivity for the MLH1, MLH2, MSH6 and PMS2 antibody stains used by the laboratory for histopathology interpretations. Refer to D5473-II. 2. Review of daily slide quality control records revealed the laboratory failed to test and document the MLH1, MLH2, MSH6 and PMS2 antibody stains for positive or negative reactivity to ensure stain quality on October 14, 2024, for the following patient that was tested and reported: Patient ID: SUR24-006103 3. During an interview in the conference room on 04/30/2025 at 10:57 a.m., the Clinical Service Manager after a review of the records confirmed the laboratory failed to test and document MLH1, MSH2, MSH6 and PMS2 stains for positive or negative reactivity to ensure stain quality each day of use for one of one day in 2024 (random review October).