Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2279872	07/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Pathology Laboratory	80 Humphreys Center Drive, Suite A, Memphis, TN	

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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual and staff interview, the laboratory failed to have a written quality assurance plan on the date of the survey (07/11/23). The findings include: 1. Observation of the laboratory on 07/11/23 at 8:15 am revealed reagents and equipment in use for performing processing and staining of tissue removed during operative procedures in preparation for microscopic examination for histopathology and cytology. 2. Review of the laboratory procedure manual revealed there was no quality assurance/quality assessment plan. 3. Interview with the laboratory director on 07/11/23 at 11:45 am confirmed the laboratory did not have a quality assurance/quality assessment plan in place for monitoring activities related to histopathology and cytology procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package inserts, lack of records and staff interview, the laboratory failed to monitor the temperature of the area where inks and stains used in preparing tissue for histopathology and cytology microscopic examination were used and stored in 2023. The findings include: 1. Observation of the laboratory revealed multiple dyes and stains in use for performing inking and staining of surgical tissue in preparation for microscopic examination. 2. Review of manufacturer package inserts revealed the following storage requirements: Hematoxylin 15-30 degrees Celsius Eosin 15-30 degrees Celsius Diff Quick -Store at room temperature Tissue Marking Dyes 15-30 degrees Celsius 3. There were no records documenting monitoring of temperature in the area where the reagents were stored. 4. Interview with the laboratory director on 07/11/23 at 11:45 am confirmed the laboratory did not monitor the temperature in the area where the histopathology and cytology reagents were stored in 2023.
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 observation of the laboratory, review of the laboratory procedure manual, patient test reports, lack of records, and staff interview, the laboratory failed to document stain quality/acceptability for two of two patients selected for review in 2023. The findings include: 1. Observation of the laboratory on 07/11/23 at 8:30 revealed the storage of reagents used for performing staining of tissue removed during operative procedures including hematoxylin and eosin (H&E), as well as Diff-Quick stain. 2. Review of the laboratory procedure manual revealed procedures for staining of tissue including the use of H&E stain and Diff-Quick stain. 3. Review of preliminary intraoperative patient test reports revealed patient 109243 performed on 05 /05/23 and patient ID 109617 performed on 06/13/23. 4. No records were available for documentation of stain quality/acceptability on the dates selected. 5. Interview with the laboratory director on 07/11/23 at 11:45 am confirmed the two patients were stained using H&E and the laboratory did not document stain quality for H&E on the selected dates. She further confirmed there is not a process in place for documenting stain quality for any of the stains used.