Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2057537	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Goodall-Witcher Hospital	101 Posey Ave, Clifton, 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 entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 direct observation, review of the Leica CM 1850 cryostat operator's manual (V2.0-03/2001), laboratory environmental records, and confirmed in interview, the laboratory failed to ensure room temperature and humidity levels were within

	specifications for the Leica CM 1850 cryostat for 645 of 645 days from 07/17/2019 through 04/21/2021. Findings included: 1. During a tour of the laboratory area on 04 /22/2021 at 10:00am, a Leica CM 1850 cryostat (Serial Number 3322012003) and a thermometer capable of room temperature and humidity measurements were observed. 2. Review of the Leica CM 1850 cryostat operator's manual (V2.0-03 /2001), stated the following in the section titled "Site Requirements": "The place of installation must meet the following requirements: Room temperature max. 35C. Air humidity must not exceed 60%. High room temperatures and excessive air humidity affect the cooling of the cryostat." 3. Review of the laboratory environmental logs from 07/17/2019 through 04/21/2021, titled "Quality Control for Frozen Sections" revealed the laboratory failed to document room temperature and humidity levels since 07/17/2019. The laboratory failed to ensure acceptable room temperature and humidity levels were within specifications for the Leica CM 1850 cryostat. 4. In an interview on 04/22/2021 at 10:15 am in the breakroom, after review of the environmental records, the laboratory representative confirmed the above findings. Word Key: Max=maximum
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 laboratory policy, laboratory quality control records, and confirmed in staff interview, the laboratory failed to document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for Hematoxylin and Eosin (H & E) staining. Findings included: 1. The laboratory policy titled "Frozen Section Staining for Goodall-Witcher Hospital" (Reviewed by the laboratory director 07/2018) stated, "Purpose: To ensure proper and consistent staining performed on frozen section tissue ...The Hematoxylin and Eosin stains are filled at CTPL lab with the same lot numbers as stains being used in the automatic stainer. These stains are monitored by use of a QC slide and reviewed by a pathologist daily." The policy failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides. 2. The laboratory quality control record titled "Quality Control for Frozen Sections" revealed a column labeled "Stain" with a check mark. The quality control record failed to define the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides. 3. In an interview on 04/22/2021 at 10:30 am in the breakroom, the laboratory representative was asked to provide documentation of the intended reactivity for the H&E stain. No documentation was provided for the intended reactivity for the H&E stain. This confirmed the above findings. Word Key: CTPL=Central Texas Pathology Laboratory QC=Quality Control