Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2157578	03/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Cpa St. David's Round Rock Hospital Pathology Dept	2400 Round Rock Ave, Round Rock, 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
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 policies and procedures, stain quality control records, patient test records and interview of facility personnel, the laboratory failed to document the intended reactivity of positive and negative control materials for the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics were achieved each day of use between January 2019 and February 2020 . Findings included: 1. Review of the laboratory's own policy titled Microscopic Examination of Anatomic Pathology Specimens (signed by the laboratory director on 04/13/2018) found under the heading Testing Accuracy and Quality Assessment : " The pathologist will review the staining and slide quality each d ay as well as the quality of the gross. If the staining quality is inadequate for diagnosis, the pathologist will request either a recut of the original tissue or request that the original slide be stained again. PL Histology Department Staff are notified of the quality issue for documentation. If the stain is still unacceptable, the pathologist will request that the technician perform the staining again and indicate what areas of the stain were unacceptable. Should the specimen fail to stain appropriately after all efforts to rectify the situation, the clinician is notified of the technical problems and the slides will be sent to an outside laboratory for review. This will be noted on the H&E Daily QC form maintained by CPL." 2. Review of the surgical and cytology Stain Quality Logs for February 2020 found the comment "good quality" documented each day in the

	column labeled CPL Surgical Case, Grossing,Processing, Embedding, Microtomy, and Stain quality. 3. Review of patient test records found no documentation of the H&E stain reactivity included in the patient report. 3. Interview of the Clinical Pathology Support Manager conducted on March 12, 2020 at 11:00 AM confirmed that testing personnel did not document the intended reactivity of H&E stains each day of use nor did the policy/ procedure define the intended reaction of positive and negative control materials.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, stain quality control records, patient test records and interview of facility personnel, the laboratory failed to document the reaction of control slides for each special and differential stain to ensure predictable staining characteristics were achieved each day of use between January 2019 and February 2020 . Findings included: 1. Review of the laboratory's own policy titled Microscopic Examination of Anatomic Pathology Specimens (signed by the laboratory director on 04/13/2018) found under the heading Testing Accuracy and Quality Assessment : " The pathologist will review the staining and slide quality each day as well as the quality of the gross. If the staining quality is inadequate for diagnosis, the pathologist will request either a recut of the original tissue or request that the original slide be stained again. PL Histology Department Staff are notified of the quality issue for documentation. If the stain is still unacceptable, the pathologist will request that the technician perform the staining again and indicate what areas of the stain were unacceptable. Should the specimen fail to stain appropriately after all efforts to rectify the situation, the clinician is notified of the technical problems and the slides will be sent to an outside laboratory for review. This will be noted on the H&E Daily QC form maintained by CPL." 2. Review of the surgical and cytology Stain Quality Logs forFebruary 2020 found the comment "good quality" documented each day in the column labeled CPL Surgical Case, Grossing,Processing, Embedding, Microtomy, and Stain quality. 3. Review of patient test records found no documentation of stain reactions included in the patient report. 3. Interview of the Clinical Pathology Support Manager conducted on March 12, 2020 at 11:00 AM confirmed that testing personnel did not document the reactions for each differential and special stain, each day of use.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: The laboratory director failed to ensure that the quality control program defined the procedure for documentation of the reactions of control materials used to ensure intended reactivity of positive and negative staining materials for all fluorescent, immunohistochemical, differential and special stains used in Histopathology testing. (see D5473 and D5601)