

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2177874	(X3) Date Survey Completed 03/02/2022
Name of Provider or Supplier Expert Pathology Consultation Services	Street Address, City, State 2840 Kellerspring Rd Suite 1104-A, Carrollton, 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	<p>Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, Quality Control (QC) logs, 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 the Hematoxylin and Eosin (H&E) QC for 20 of 20 days in 2021 (random review 12 /2021) and 39 of 39 days in 2022 (01/2022 through 03/2022). Findings: 1. Review of</p>

the laboratory's policy "Quality Management" revealed: "POLICY Review of all specimens and accompanying requisitions for accuracy. Quality control sheets for all slides and special stains will be filled as needed. All special stains performed in the pathology laboratory will have a control slide that is checked daily by the Pathologist. Each batch of slides processed with IHC will have a positive and a negative control slide accompanied throughout the process of staining and will be checked by the Pathologist. If a slide technical issue is noted, it shall be documented in a QC log and submitted to the corresponding Laboratory for corrective action." The policy did not define intended reactivity of the H&E stain to ensure predictable characteristics. 2. Review of the "Daily H & E Control Log" revealed the following: The log had a column for "ADEQUATE STAINING" and each day QC was documented with a "checkmark" in the column. The following dates in 2021 (random review) and 2022 were observed to be documented with a "checkmark": 2021 December: 1, 2, 3, 6, 7, 8, 9, 10, 13, 14, 15, 16, 17, 20, 21, 22, 23, 28, 29, 30 2022 January: 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 17, 18, 19, 20, 21, 24, 25, 26, 27, 28, 31 February: 1, 2, 6, 7, 8, 9, 10, 11, 14, 15, 16, 17, 18, 21, 22, 23, 25, 28 March: 1 The laboratory failed to document the staining characteristics for the H&E stain. 3. Review of test volume records provided by the laboratory included a total annual volume of 45,000 histopathology tests. 4. During an interview on 03/02/2022 at 10:25 am, the Laboratory Director confirmed the above findings.