

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0690270	(X3) Date Survey Completed 02/24/2021
Name of Provider or Supplier Professional Technology Laboratory	Street Address, City, State 1055 Evergreen Circle, The Woodlands, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were 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.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records from 2020 and confirmed in interview, the laboratory failed to verify twice annually 4 of 4 IHC and special stains performed: S-100; AK-AE1-AE2/3; CK-20; and PAS. Findings were: 1. Random review of the laboratory patient test records from January to December 2020 revealed the laboratory performed the following 4 IHC and special stains: S-100; AK-AE1-AE2/3; CK-20; and PAS. 2. Review of the laboratory records from 2020 revealed no documentation of the twice annual verification of the above stains. 3. An interview with the laboratory director on 2/24/21 at 1050 hours in the conference room confirmed the above findings. key: S-100 - immunostain marking the sustentacular cells in a paraganglioma. Several members of the S100 protein family are useful as markers for certain tumors and epidermal differentiation AK-AE1-AE2/3 - cytokeratin antibody stains CK-20 - Immunohistochemical staining of cytokeratin 20 PAS - Periodic Acid Schiff IHC - Immunohistochemistry</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</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.

This STANDARD is not met as evidenced by:

Based on review of laboratory patient test records and quality control records and confirmed in interview, the laboratory failed to document the slide quality of the Hemotoxin and Eosin (H & E) differential stain each day of patient testing for 7 of 10 days reviewed. Findings were: 1. Random review of the quality control log for the H & E stain from January 2020 to December 2020 revealed no documentation of the slide quality for the H & E stain for the following 7 of 10 days reviewed: 2/10/20, 8/12/20, 9/17/20, 10/29/20, 10/19/20, 11/18/20, 9/9/20. 2. Review of the above dates revealed the laboratory interpreted H&E stain for the following 8 patients with no documentation of the slide quality of the control slide. Date 2/10/20 TW20-105 TW20-112 Date 8/12/20 TW20-524 Date 9/17/20 Accn TW20-589 Date 10/29/20 Accn TW20-663 Date 10/19/20 Accn TW20-642 Date 11/18/20 Accn TW20-741 Date 9/9/20 Accn TW20-570 3. An interview of the laboratory director on 2/24/21 at 1050 hours in the conference room confirmed the above findings. He stated that he has only been documenting the stain quality for batches of slides reviewed, not every day of testing.

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 the laboratory patient test records and quality control records from 2020, and confirmed in interview, the laboratory failed to document the positive and negative reactivity every day of patient testing for 4 of 4 IHC and special stains performed: S-100; AK-AE1-AE2/3; CK-20; and PAS. Findings were: 1. Random review of the laboratory patient test records from January to December 2020 revealed the laboratory performed the following 4 IHC and special stains: S-100; AK-AE1-AE2/3; CK-20; and PAS. 2. Random review of the laboratory patient records from January to December 2020 revealed no documentation of the positive and negative reactivity of the quality control slides of the following IHC stains for 2 of 5 records reviewed. Date 11/18/20 Accn TW20-741 S-100 AK-AE1AE2/3 Date 09/20/20 Accn TW20-570 S-100 CK-20 3. An interview with the laboratory director on 2/24/21 at 1050 hours in the conference room confirmed the above findings. He acknowledged that he needs to document the control. key: S-100 - immunostain marking the sustentacular cells in a paraganglioma. Several members of the S100 protein family are useful as

markers for certain tumors and epidermal differentiation AK-AE1-AE2/3 -
cytokeratin antibody stains CK-20 - Immunohistochemical staining of cytokeratin 20
PAS - Periodic Acid Schiff IHC - Immunohistochemistry

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records, and confirmed in interview, the laboratory failed to have a quality assurance plan to identify and correct problems in analytic systems. Refer to D5473, D5601