

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2080542	(X3) Date Survey Completed 09/27/2018
Name of Provider or Supplier Premier Histology Of Texas Llc	Street Address, City, State 15058 Beltway Dr Suite 113, Addison, 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 deficiency and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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
D6143	<p>GENERAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1461</p> <p>(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii)</p>

Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

A. Based on staff interview, review of laboratory records, and review of patient test reports, the General Supervisor failed to review ALL specimen physical examinations /descriptions of tissue including color, weight, measurement and other characteristics of the tissue. Findings included: 1. During an interview on 09/27/2018 at 1200 hours, testing person #1 revealed that each day of testing the specimen slides were submitted for evaluation along with the form titled "Pathologist QC Log for Technical Evaluation of Tissue Slides." The testing person further explained that ONE form was submitted for ALL specimens grossed on a specific day. It was NOT used to review individual specimen grossing. 2. Review of the laboratory form titled "Pathologist QC Log for Technical Evaluation of Tissue Slides" revealed the form included a check off area labeled "Summary report on quality of slide preparation for the entire day's work". The form also included the following items to be evaluated as acceptable by checking "Y" for yes and "N" for no: a. Fixation Acceptable Y N b. Grossing Acceptable Y N c. Processing Acceptable Y N d. Embedding Acceptable Y N e. Microtomy Acceptable Y N f. Staining Acceptable Y N g. Coverslipping Acceptable Y N h. Labeling/Specimen ID Acceptable Y N 3. A random review of patient test

records and the "Pathologist QC Log for Technical Evaluation of Tissue Slides" forms from 07/25/2018 through 09/19/2018 revealed 26 of 26 days with no documentation for review of the grossing for ALL patient specimens by the General Supervisor (GS). The following test reports were submitted: a. Date: 07/25/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01788 Patient PH18-01793 Patient PH18-01794 b. Date: 07/30/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01818 Patient PH18-01819 c. Date: 08/01/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01823 Patient PH18-01824 Patient PH18-01826 d. Date: 08/02/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01855 Patient PH18-01848 e. Date: 08/07/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01873 Patient PH18-01880 Patient PH18-01884 Patient PH18-01885 Patient PH18-01886 Patient PH18-01887 Patient PH18-01893 Patient PH18-01894 Patient PH18-01895 f. Date: 08/10/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01928 Patient PH18-01929 Patient PH18-01932 Patient PH18-01933 Patient PH18-01934 Patient PH18-01936 g. Date: 08/16/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01977 Patient PH18-01985 Patient PH18-01986 Patient PH18-01987 Patient PH18-01988 Patient PH18-01989 h. Date: 08/17/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-01990 Patient PH18-01991 Patient PH18-01992 Patient PH18-01993 Patient PH18-01994 Patient PH18-01995 Patient PH18-01997 Patient PH18-01998 Patient PH18-01999 Patient PH18-02000 Patient PH18-02001 Patient PH18-02002 Patient PH18-02003 Patient PH18-02004 Patient PH18-02005 Patient PH18-02006 Patient PH18-02007 Patient PH18-02008 i. Date: 08/20/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02010 Patient PH18-02011 Patient PH18-02012 j. Date: 08/22/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02042 Patient PH18-02043 Patient PH18-02044 Patient PH18-02045 Patient PH18-02048 Patient PH18-02049 Patient PH18-02051 k. Date: 08/23/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02058 Patient PH18-02059 Patient PH18-02060 Patient PH18-02064 l. Date: 08/24/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02065 Patient PH18-02066 Patient PH18-02067 Patient PH18-02071 Patient PH18-02072 m. Date: 08/27/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02073 Patient PH18-02076 Patient PH18-02077 n. Date: 08/28/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02087 Patient PH18-02088 Patient PH18-02089 Patient PH18-02090 Patient PH18-02091 Patient PH18-02093 Patient PH18-02094 o. Date: 08/29/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02097 Patient PH18-02085 p. Date: 08/31/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02130 Patient PH18-02135 Patient PH18-02136 Patient PH18-02137 Patient PH18-02139 Patient PH18-02141 Patient PH18-02142 Patient PH18-02143 Patient PH18-02144 Patient PH18-02145 q. Date: 09/04/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02138 Patient PH18-02140 Patient PH18-02146 Patient PH18-02148 Patient PH18-02149 Patient PH18-02150 r. Date: 09/06/2018 No specific slide number documented on form. The

following patients were processed on this date: Patient PH18-02188 Patient PH18-02189 Patient PH18-02190 Patient PH18-02191 Patient PH18-02192 Patient PH18-02199 Patient PH18-02200 s. Date: 09/10/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02211 Patient PH18-02213 Patient PH18-02214 Patient PH18-02215 t. Date: 09/11/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02221 Patient PH18-02223 Patient PH18-02224 Patient PH18-02227 Patient PH18-02228 Patient PH18-02229 Patient PH18-02230 Patient PH18-02231 Patient PH18-02232 Patient PH18-02233 Patient PH18-02234 Patient PH18-02235 Patient PH18-02236 Patient PH18-02237 Patient PH18-02238 Patient PH18-02239 u. Date: 09/12/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02245 Patient PH18-02246 Patient PH18-02247 Patient PH18-02248 Patient PH18-02249 Patient PH18-02250 Patient PH18-02251 Patient PH18-02254 Patient PH18-02255 Patient PH18-02256 v. Date: 09/13/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02259 Patient PH18-02260 Patient PH18-02261 Patient PH18-02262 Patient PH18-02263 Patient PH18-02270 w. Date: 09/14/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02271 Patient PH18-02272 Patient PH18-02273 Patient PH18-02274 Patient PH18-02278 Patient PH18-02279 Patient PH18-02280 Patient PH18-02283 x. Date: 09/17/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02275 Patient PH18-02291 Patient PH18-02292 Patient PH18-02294 y. Date: 09/18/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02300 Patient PH18-02305 Patient PH18-02307 Patient PH18-02308 Patient PH18-02310 Patient PH18-02311 Patient PH18-02312 Patient PH18-02318 Patient PH18-02320 Patient PH18-02323 Patient PH18-02324 z. Date: 09/19/2018 No specific slide number documented on form. The following patients were processed on this date: Patient PH18-02325 Patient PH18-02327 Patient PH18-02328 Patient PH18-02329 Patient PH18-02332 Patient PH18-02333 Patient PH18-02335 Patient PH18-02337 Patient PH18-02338 Patient PH18-02340 Patient PH18-02344 Patient PH18-02346 3. The above findings were confirmed in an interview with laboratory staff on 09/27/2018 at 1200 hours in the laboratory. B. Based on form CMS-209, review of laboratory records (08/15/2018-09/19/2018), and staff interview, the General Supervisor (GS) named on the CMS-209 failed to review physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue. Findings included: 1. Review of form CMS-20 revealed that an individual other than the General Supervisor named on the CMS-209 form signed the laboratory form titled "Pathologist QC Log for Technical Evaluation of Tissue Slides" for the following 11 of 19 days of specimen processing (random review from 08/15/2018 through 09/19/2018): a. 08/15/2018 b. 08/17/2018 c. 08/20/2018 d. 08/23/2018 e. 08/24/2018 f. 09/06/2018 g. 09/12/2018 h. 09/13/2018 i. 09/14/2018 j. 09/17/2018 k. 09/19/2018 2. Review of the laboratory form titled "Pathologist QC Log for Technical Evaluation of Tissue Slides" revealed the form was NOT signed and, therefore, had NO documentation of slide review for the following 1 of 19 days of specimen processing (random review from 08/15/2018 through 09/19/2018): a. 08/22/2018 3. In an interview on 09/27/2018 at 1230 hours in the laboratory, testing person#1 stated that the GS was not always the person who read and reviewed the specimen slides. This confirmed the above findings. C. Based on review of laboratory records and staff interview, it was revealed the General Supervisor (GS) failed to document review of specimen physical examinations /descriptions of tissue including color, weight, measurement and other characteristics of the tissue. Findings included: 1. Review of the laboratory form titled "Pathologist

QC Log for Technical Evaluation of Tissue Slides" revealed the form included a check off area labeled "Summary report on quality of slide preparation for the entire day's work". The form also included the following conditions to be evaluated as acceptable by checking "Y" for yes and "N" for no: a. Fixation Acceptable Y N b. Grossing Acceptable Y N c. Processing Acceptable Y N d. Embedding Acceptable Y N e. Microtomy Acceptable Y N f. Staining Acceptable Y N g. Coverslipping Acceptable Y N h. Labeling/Specimen ID Acceptable Y N 2. A random review of the QC log (07/25/2018-09/19/2018) revealed 13 of 33 logs signed by the General Supervisor that failed to document review of grossing for ALL patient specimens and also failed to indicate acceptable conditions by checking Y or N for the following dates: 07/25/2018 07/30/2018 08/01/2018 08/02/2018 08/03/2018 08/07/2018 08/10/2018 08/14/2018 08/16/2018 08/17/2018 08/27/2018 08/28/2018 08/29/2018 3. During an interview with testing person #1 on 09/27/2018 at 1230 hours in the laboratory, the testing person #1 contacted the GS by phone and asked what the signature on the form indicated. The GS responded that the signature meant nothing. This confirmed the above findings.