

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0478897	(X3) Date Survey Completed 11/22/2019
Name of Provider or Supplier Southwestern Women's Surgery Center	Street Address, City, State 11884 Greenville Ave Suite A111, Dallas, 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	The Co-Director of Nursing and the Administrator were at the entrance conference conducted 11/22/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Co-Director of Nursing and the Administrator on 11/22/2019. 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.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, and in interview with staff, the laboratory failed to follow manufacturer's instructions for the storage of HemoPoint H2 optics cleaner used on the HemoPoint H2 meter (for waived hemoglobin test). Findings included: 1. During a tour of the facility on 11/22/2019 at 10:53 am, a bag by Stanbio Laboratory with 5 HemoPoint H2 optic cleaners (unopened; Lot #192051, expiration date 10/31/2020) and storage requirements of 15-30 degrees Celsius was observed to be stored in the refrigerator at 40 degrees Fahrenheit (4.4 degrees Celsius). 2. Review of the HemoPoint H2 Optics Cleaner manufacturer's instructions stated, "Storage and Stability: The Optical Cleaner is stable until the expiration date, when stored unopened at 59 - 86 degrees F (15-30 degrees C). After opening, the cleaner must be used within 10 minutes." The laboratory did not follow manufacturer's instructions for the 15-30 degree Celsius</p>

storage of the unopened HemoPoint H2 optics cleaners. 3. During an interview on 11/22/2019 at 10:53 am, the Co-Director of Nursing confirmed the HemoPoint H2 optics cleaners were not stored according to the manufacturer's requirements.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of American Proficiency Institute (API) proficiency testing (PT) documents and in interview with staff, the laboratory failed to document the review and evaluation of Rhesus factor (Rh) test results obtained on PT performed for 3 of 3 testing events in 2018 (2018-1, 2018-2, 2018-3) and 2 of 2 testing events in 2019 (2019-1, 2019-2). Findings included: 1. Review of API PT documents for 2018 and 2019 revealed the laboratory did not ensure the laboratory director/technical consultant documented their review/evaluation of Rh PT results, as follows: 2018- 1 - performance review document was not signed 2018 -2 - performance review document was not signed 2018 -3 - performance review document was not signed 2019 -1 - performance review document was not signed 2019 -2 - performance review document was not signed 2. During an interview on 11/22/2019 at 9:55 am, Co-Director of Nursing and the Administrator reviewed and confirmed the above findings.