Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2035109	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gwu Medical Faculty Associates	2150 Pennsylvania Avenue, Nw Pft Lab 3-133, Washington, DC	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of Radiometer instructions (the manufacturer of calibration solution for ABL80 CO-OX machine), the laboratory's procedure for the tests performed in this laboratory, and confirmation by interview with the Testing Personnel, the laboratory failed to develop a temperature monitoring mechanism for the storage of the calibration solution for ABL80 CO-OX machine. The findings included: 1. Review of the manufacturer's instructions for ctHb calibration solution revealed instructions to store the solution for 24 months at 2-25 degrees centigrade (C) and for up to 14 days at a temperature up to 32C. In addition, the manufacturer further provide instructions to store the ampoules at a constant temperature between 18C and 32C for 5 hours before use. 2. Review of the laboratory's policies and procedures manual did not include a temperature monitoring for storage of ctHb calibration solution. 3. According to interview with the Testing Personnel, on 9/13/18 at approximately 1:30 PM, although there is a wall thermometer in the calibration storage room, the temperature is not monitored or documented.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on interview with Testing Personnel (TP) and representative of the proficiency test provider and review of the laboratory's proficiency testing (PT) results from the American Proficiency Institute (API), the Laboratory Director (LD) failed to ensure that the laboratory is re-enrolled in a timely manner to participate in a PT for Hemoglobin for one (1) testing event in 2018 (first testing event). The findings included: 1. Review of PT results from API (the laboratory's proficiency testing provider) for 2018 revealed that the laboratory did not participate in the PT for Blood gas and Blood Oximetry for the first testing event for lack of re-enrolment. 2. Interview with the TP on 9/13/18 at approximately 3:00 PM revealed that the laboratory did not re-enroll in API in a timely manner for 2018 due to miscommunication with API. Further interview with the TP revealed that the laboratory requested to cancel the third testing event in 2017 due to the staff traveling out of the country. The TP was under the assumption that re-enrollment was automatic. Although the laboratory obtained remedial sample for Blood Gas, was unable to get remedial sample for Blood Oximetry (that included hemoglobin). 3. Telephone interview with API representative on 9/21/18 (post the exit conference) confirmed that API did not send notice to the laboratory to enroll for 2018. According to API representative, the laboratory notified API that testing Blood Gas and Blood Oximetry test was to be discontinued on 8/27/17 and did not specify when the testing will resume. Further interview with API representative revealed that the laboratory requested for remedial sample for Blood Gas and Blood Oximetry on 4/10/18. API sent samples for Blood Gas but not for Blood Oximetry. According to the representative for API, samples for Blood Oximetry were unavailable on 4/10/18.