

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2134259	<b>(X3) Date Survey Completed</b> 01/22/2020
<b>Name of Provider or Supplier</b> Health And Wellness Solutions, Pa	<b>Street Address, City, State</b> 1259 Fm 1463, Suite 500, Katy, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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. 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.
<b>D5217</b>	<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's quality assurance records from 2019 and 2020 and staff interview, it was revealed the laboratory was missing 1 of the 2 accuracy assessments for 1 of 1 tests (grossing) in 2019. The findings were: 1. A review of the laboratory's quality assurance records from 2019-2020, revealed no documentation of the 2nd accuracy assesment for grossing in 2019. 2. An interview with the laboratory consultant on 01/22/2020 at 1030 hours in the break room revealed the laboratory performed the accuracy assessment only once in 2019. This confirmed the findings.</p>
<b>D5291</b>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p>

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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on a lack of written laboratory policies and staff interview, the laboratory failed to establish and monitor problems in general lab systems. The findings include: 1. The laboratory's quality assurance policy revealed no documentation of a policy to document the twice annual accuracy assessment. refer to D5217

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on review of 10 random patient test reports from testing performed in August 2019 through January 2020, and staff interview, it was revealed the laboratory failed to ensure the test report included the name and address of the laboratory where testing was performed on 10 of 10 reports. The findings were: 1. A review of 10 random patient test reports from testing performed in August 2019 through January 2020 revealed 10 of 10 test reports failed to include the name and address of the testing laboratory. The specimen identification numbers and test dates reviewed were:  
Specimen # Date Reviewed 0686 08/19/2019 0745 09/09/2019 0857 10/11/2019 0888 10/18/2019 0927 10/30/2019 0962 11/11/2019 0984 11/15/2019 1067 12/06/2019 1148 12/31/2019 0032 01/19/2020 2. An interview with the laboratory consultant on 01/22/2020 at 1130 hours in the break room, confirmed the name and address of the testing laboratory was not present on its test reports. He is currently working with the LIS to add this information.

**D6121**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:  
Review of competency assessment records and laboratory representative interview revealed the laboratory technical supervisor failed to evaluate the competency assessment for 1 of 1 testing personnel in the laboratory facility. Findings included: 1.

Review of the laboratory 2019 records for Grossing Competency Assessment revealed that competency was performed by the LD on (TP #1 on the CMS-209) in August 2019 at a different laboratory (does not state which laboratory). The LD log indicates he was only on site 11/11/2019. 2. The above findings were confirmed in an interview with laboratory consultant on 01/22/2020 at 1100 in the break room. He acknowledged that the competency documented was performed at another lab. Key LD - Laboratory Director TP - Testing Person

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**  
CFR(s): 493.1461

(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) 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:

Based on a lack of laboratory policy, review of patient test reports, and interview with laboratory representative, the technical supervisor failed to review all specimens within 24 hours after grossing. Findings included: 1. Review of laboratory policy on 01/22/2020, revealed there's no documentation of a policy for reviewing specimens within 24 hours after grossing tissue slides. 2. Review of random patient test reports from August 2019 through January 2020, revealed 5 of 10 patients reports were not documented within 24 hours after grossing. 10 patients reviewed were grossed by the testing person who's not qualified as a TS; therefore, requires the 24 hour review. Specimen Date grossed Date reviewed 0686 08/15/19 08/19/19 0745 09/05/19 09/09/19 0927 10/28/19 10/30/19 0962 11/07/19 11/11/19 0032 01/15/2020 01/19/2020 3. During an interview with laboratory consultant on 01/22/2020 at 1130 hours in the break room, he confirmed the technical supervisor was not reviewing all specimens within 24 hours. Key TS - Technical Supervisor