Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0876744	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Advanced Women's Care Of Pgh	**Street Address, City, State** 3928 Washington Rd, Suite 230, Mcmurray, PA	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the testing personnel (TP) #9 (CMS-209 form personnel #9), the laboratory failed to provide 2 of 6 PT attestation statements for mycology, parasitology, and bacteriology signed by the laboratory director or designee in 2021 and 2022. Findings include: 1. On the day of the survey, 10/17/2023 at 02:20 pm, the following API PT attestation statements were not signed by the laboratory director or designee in 2021 and 2022: - 2021, Event #3, Mycology, Parasitology, and Bacteriology. - 2022, Event #2, Mycology, Parasitology, and Bacteriology. 2. The TP #9 confirmed the findings above on 10/17/2023 around 3:10 pm.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with the testing personnel (TP) #9 (CMS-209 form personnel #9), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which patient tests were being performed from

	08/24/2021 to the date of the survey. 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. The laboratory performs patient testing Monday from 08:00 am to 06:00 pm, Tuesday through Thursday from 08:00 am to 04:00 pm, and Friday from 08:00 am to 03:00 pm according to the information in the CMS-116 form. 3. Review of the laboratory personnel report (Pennsylvania State) form on 10/17 /2023 showed that the laboratory director (LD) acts as the only general supervisor for the laboratory. 4. On the day of the survey, 10/17/2023 at 01:38 pm, during an interview, the TP#9 stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing according to chapter 5 section 5.23 of the Pennsylvania State regulations for clinical laboratories.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the testing personnel (TP) #9 (CMS-209 form personnel #9), the laboratory failed to verify twice annually the accuracy of Potassium Hydroxide (KOH) and Wet preps microscopic examinations from 08/24/2021 to the date of the survey. Findings include: 1. On the day of survey, 10/17/2023 at 01:57 pm, the laboratory could not provide documentation of verification of accuracy for KOH and Wet preps microscopic examinations performed from 08/24/2021 to the date of the survey. 2. The laboratory reported a total of one test that was performed since 08/24/2021. 3. The TP #9 confirmed the findings above on 10/17/2023 around 3:10 pm.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the testing personnel (TP) #9 (CMS-209 form personnel #9), the laboratory failed to ensure that an expired reagent, Potassium Hydroxide (KOH), was not used beyond the expiration date from 09/30/2021 to the date of the survey. 1. On the date of the survey, 10/17/2023 at 03:05 pm, the laboratory tour revealed that the following reagent used for KOH/Wet prep examinations were expired: - 1 bottle of KOH 10% w/v MCC Medical Chem Corp. expired : 09/30/2021 2. The laboratory performed one KOH/Wet prep examination from 09/30/2021to 10/17/2023. 3. The TP #9 confirmed the findings above on 10/17 /2023 around 3:10 pm.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of laboratory procedure manual, observation of the microscope and interview with the testing personnel (TP) #9 (CMS-209 form personnel #9), the laboratory failed to establish a maintenance protocol for the 1 of 1 microscope used for the microscopic examinations for Potassium Hydroxide (KOH) and Wet Preps from 08/24/2021 to the date of the survey. Findings include: 1. At the time of the survey, on 10/17/2023 at 02:40 pm, the review of documentation revealed that the last maintenance performed on the microscope was on 03/38/2023. 2. The laboratory failed to provide a written maintenance protocol for the microscope in use. 3. The TP #9 confirmed the findings above on 10/17/2023 around 3:10 pm.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on record review and interview with testing personnel (TP) #9 (CMS-209 form personnel #9), the LD failed to follow and document quality control (QC) according to the manufacturer's instructions for CLIA-waived Sysmex Multistix Reagent Strips from 08/24/2021 to the date of the survey. Findings Include: 1. The Sysmex MultiStix Reagent Strips manufacturer instructions stated for CLIA-Waived Laboratories: "Test positive and negative quality controls with new lots, new shipment of reagents, and when you open a new bottle of reagent strips. Test reagents monthly that are stored for more than 30 days. Run QC tests to ensure reagent storage integrity; train new users: confirm test pertormance: and when patients' clinical conditions or symptoms do not malch. Also, run QC tests per your laboratory procedures." 2. On the day of survey, 10/17/23 at 01:43 pm, the laboratory failed to provide documentation of QC performed for the waived Siemens multistix 10 strip between 8/24/21 to 10/17/23. 3. The laboratory urinalysis test volumes for 2022 and 2023 were: 2022: 2856 2023: 1872 4. The above findings were confirmed by TP #9 in interview on 10/17/23 at 1:43 pm. B. Based on record review and interview with TP #9, the LD failed to follow and document quality control (QC) according to the laboratory's IQCP for the BD Affirm VPIII. Findings Include: 1. On the date of inspection 10/17/23, the laboratory provided an IQCP for BD Affirm VPIII. The laboratory's IQCP states that: "QC must be performed with each new lot number, that Internal QC is "acceptable" for each patient test performed, and that normal and abnormal control levels, per manufacturer instructions, must be run every 30 days." 2.

	On the date of inspection 10/17/23, the laboratory failed to provide complete documentation of QC for the BD Affirm for 2022. QC Dates were missing for: - May 2022 - June 2022 - July 2022 - August 2022 - September 2022 3. The laboratory reported 527 BD Affirm VPIII test results in 2022. 4. The above findings were confirmed by TP #9 in an interview on 10/17/23 at 02:32 pm. C. Based on record review and interview with TP #9, the LD failed to ensure that quality assessment (QA) programs were established and maintained to identify failures in quality as they occur from 08/24/21 to 10/17/23. Findings include: 1. On the date of survey, the laboratory failed to provide a Quality Assessment (QA) policy. 2. On the date of survey, the laboratory failed provide documentation of QA activities performed in 2022 and 2023. 3. The above findings were confirmed by TP #9 in an interview on 10 /17/23 at approximately 2:53 pm.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the competency assessment records and interview with the testing personnel (TP) #9 (CMS-209 form personnel #9), the technical consultant (TC) failed to evaluate and document the annual competency for 9 of 12 testing personnel (TP) in 2022 and 2 of 12 testing personnel (TP) in 2023 who performed Potassium Hydroxide (KOH) and Wet Preps microscopic examinations from 08/24/2021 to the date of the survey. Findings include: 1. On the day of survey, 10/17/2023 at 01:13pm, the laboratory could not provide the annual competency assessment records for 9 of 12 TP and 2 of 12 TP who performed Potassium Hydroxide (KOH) and Wet Preps microscopic examinations in 2022 and 2023, respectively. 2. The TP #9 confirmed the findings above on 10/17/2023 around 3:10 pm.