Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2151985	01/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Labsolutions, Llc	3729 Easton Nazareth Highway Suite Ll1, Easton, 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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, interview with Laboratory Director (LD) and General Supervisor (GS), the current laboratory director failed to approve procedures prior to the start of patient testing on 01/14/2019. Findings include: 1. On the day of survey, 01/28/2019, review of procedure manuals revealed the LD signed the procedures manuals on 01/26/2019 while patient testing began on 01 /14/2019. 2. From 01/14/2019 to 01/28/2019, 1000 patient tests were run. 3. The LD confirmed the labortaory started patient testing before the LD signed all procedures on 1/28/2019 around 9:30 am.
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 review of maintenance records, observation of labortaory equipment, interview with the laboratory director (LD) and general supervisor (GS), the laboratory failed to produce a maintenance policy and document the maintenance of 7 of 8 pieces of equipment used for patient testing in 2019. Findings include: 1. On the day of survey, 01/28/2019, observation of equipment maintenance stickers revealed: - 1 of 1 Alkali Scientific Inc. (ASI) Mini Spin 6 centrifuge last calibration was performed on 05/08/2017 and due on 05/08/2018. - 3 of 3 Mettler Toledo Rainin Pipet - Lite XLS+ pipettes were due for calibration: a. pipette #36 - 2 ul - 20 ul single b. pipette #41 - 100 ul - 1 ml single c. pipette #27 - Multichannel 2 ul - 20 ul - 2 of 3 MarketLab thermometers used to monitor the temperature of refrigerators and/or freezers containing instrument reagents and controls: a. ML13163, S/N 130573852, last calibrated on 11/30/2017, due on 11/30/2018. b. ML13163, S/N 150683445, last calibrated on 11/30/2017, due on 11/30/2018. - 1 of 1 PGX 36 well plates, calibration was lasted performed on 01/23/2018 and due on 01/23/2019. 2. On 01/28/2019 around 11:30, the LD and GS confirmed recent equipment calibration was not performed and that the labortaory did not have a equipment maintenance policy.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the BioFire FilmArray, Respiratory Panel 2 (RP2) Individual Quality Control Program (IQCP) procedure, interview with laboratory director (LD) and General Supervisor (GS), the laboratory director failed to ensure a complete IQCP plan was put into place before patient testing began on 01/14/2019. Findings Include: 1. On the day of survey, 01/28/2019, review of the The BioFire FilmArray, Respiratory Panel 2's IQCP revealed: a. A comprehensive procedure that described the steps of the Risk assessment worksheet was missing. b. Documentation of the Quality Control Plan providing immediate detection of errors for each phase of the patient testing process (i.e. before, during, and after testing) for the BioFire FilmArray Respiratory Panel 2 (RP2) test was missing. c. Missing a Quality Assessment Plan. d. The LD did not sign the IQCP before patient testing began on 01/14/2019. 2. The LD and GS confirmed the findings above on 01/28/2019 around 12:30 pm.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory personnel training records, interview with Laboratory Director (LD) and General Supervisor (GS), the LD failed to ensure that prior to testing patients' specimen, testing personnel (TP) #1 through #5 received initial

	training in 2019. Findings include: 1. On the day of survey, 1/28/2019, the laboratory was unable to provide records of training performed for TP #1 - #5 prior to the start of patient testing of Chemistry, Bacteriology and Virology tests on 01/14/2019. 2. The LD confirmed on 01/28/2019 at 11:15 am that no training was performed for all testing personnel running patient samples at this site.