Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0856468	02/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lancaster Family Medical Center Sc	9177 Old Potosi Rd, Lancaster, WI	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records and interview with laboratory personnel, one of the two testing personnel who routinely interpret microbiology cultures did not test any of the proficiency samples in the three events in 2018. Findings include: 1. Review of PT records from the three microbiology events in 2018 showed the laboratory director evaluated and reported the culture results from all five samples in each event. The laboratory provided no evidence showing the second testing personnel, staff B, examined any of the proficiency testing samples in 2018. 2. Interview with laboratory personnel, staff A, on February 6, 2019 at 11:00 AM confirmed the laboratory director and staff B routinely evaluate and report patient microbiology culture results. Further interview confirmed the second testing personnel, staff B, did not perform any of the microbiology proficiency sample testing in 2018.
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 surveyor review of proficiency testing (PT) attestation statements and interview with laboratory personnel, the laboratory director did not sign the attestation statements for five of the six microbiology events in 2017 and 2018. Findings include: 1. Review of PT attestation statements for the six microbiology events in 2017 and 2018 showed the laboratory director (who was also the technical consultant) did not attest to the routine integration of the samples into the patient workload using the laboratory's routine methods for events one, two, and three in 2017 and events one and two in 2018. 2. Interview with laboratory personnel, staff A, on February 6, 2019 at 11:00 AM confirmed the laboratory director did not sign the attestation statements for the three microbiology events in 2017 or the first two events in 2018. This is a repeat deficiency previously cited on April 26, 2017.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing records from the third microbiology event in 2018 and interview with laboratory personnel, testing records for five of five samples were not retained. Findings include: 1. Review of the API (American Proficiency Institute) proficiency testing report for the third microbiology event in 2018 showed the laboratory cultured samples TH-11, 12, and 13 for Group A Streptococcus and samples UR-11 and 12 for urine colony count and presumptive classification. Review of the laboratory records for this event showed no evidence the laboratory retained the testing records for these five cultures. 2. Interview with laboratory personnel, staff A, on February 6, 2019 at 11:45 AM confirmed the laboratory did not retain the testing records for the five culture samples in the third microbiology proficiency testing event in 2018.
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 surveyor review of the IQCP (Individualized Quality Control Plan) for microbiology media and interview with laboratory personnel, the laboratory director did not sign and date the Quality Control Plan before use. Findings include: 1. Review of the IQCP for microbiology media (printed October 9, 2018) revealed no evidence of review or approval by the laboratory director. 2. Interview with laboratory personnel, staff A, on February 6, 2019 at 11:45 AM confirmed the director did not sign and date the IQCP before putting it into use.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its

	ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Individualized Quality Control Plan (IQCP) for culture media and quality control records, review of the plan of correction submitted after the last survey, and interview with laboratory personnel, the laboratory did not document quality control for throat or urine culture media or develop an IQCP for culture media until October 2018. Findings include: 1. Review of the laboratory's IQCP for culture media, printed on October 9, 2018, showed the laboratory director did not sign or date the IQCP. (See D5407) 2. Review of microbiology quality control records showed no evidence of quality control evaluation of each batch of media or bacitracin disks prior to October 2, 2018. 3. Review of the plan of correction submitted in response to the citation at D5477 at the April 26, 2017 CLIA (Clinical Laboratory Improvement Amendments) survey (Event: H4SE) showed the laboratory would develop an IQCP for microbiology media by August 31, 2017. 4. Interview with laboratory personnel, staff A, on February 6, 2019 11:45 AM confirmed the laboratory did not develop an IQCP for bacteriology media until October 2018 and did not document the performance of quality control of culture media or bacitracin disks prior to October 2, 2018. This is a repeat deficiency previously cited on April 26, 2017.