Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0723560	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Starling Physicians Pllc	300 Kensington Ave, New Britain, CT	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency records on 10/29/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the technical consultant and clinical consultant. b. The laboratory did not have competency documentation for the above laboratory personnel. 2. Staff interview with the technical consultant on 10/29/19 at 10:45 AM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to follow established laboratory procedure for new reagent lot verification in the

	specialty of hematology. Findings include: 1. Record review of the "Pochi lot to lot verification (Reagent Validation)" procedure on 10/29/19 revealed: a. New reagent lots need to be tested in parallel with old lots before being placed in service. b. Testing personnel (TP) are to repeat two patient specimens from the old lot with the new lot and document on the new reagent lot validation worksheet. c. Acceptable difference on all specimens must be +/- 20% before new reagent is placed in service. 2. Surveyor observation of the Sysmex PocH 100i Complete Blood Count (CBC) analyzer, Serial Number G4929 on 10/29/19 at 10:50 AM revealed the following on board reagents: a. pocH pack D Lot # Y9020: handwritten on side of container received: 9/25/19; opened 10/28/19. b. pocH pack L Lot # Y8007: handwritten on label opened 10/3/19. 3. Record review of the New Reagent Lot Validation Worksheets on 10/29/19 revealed: a. One worksheet dated 12/29/17 for PocH Pack L reagent. b. One worksheet dated 2/2/18 for PocH Pack D reagent. c. One worksheet not dated and unknown for which reagent type. d. The above worksheets did not contain % difference; whether results were acceptable and were not reviewed and approved. 4. Staff interview with TP #1 on 10/29/19 at 11:00 AM stated he/she was unaware of the procedure when changing reagent lots and although a clipboard containing the new reagent lot validation worksheets was posted next to the instrument, it was not being used. 5. The laboratory performs 2,593 CBC tests annually. This is a repeat deficiency.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to label reagents with the appropriate expiration dates in the specialty of hematology. Findings include: 1. Surveyor observation of the Sysmex PocH 100i Complete Blood Count (CBC) analyzer, Serial Number G4929 on 10/29/19 at 10:50 AM revealed the following on board reagents: a. pocH pack D Lot # Y9020: handwritten on side of container received: 9/25/19; Opened 10/28/19; Expiration 1/11 /21. b. pocH pack L Lot # Y8007: handwritten on label opened 10/3/19; expiration date printed on manufacturer label 12/26/19. 2. Record review of the PocH-100i Procedure manual on 10/29/19 revealed: a. pocH pack D: Unopened stable to expiration date on manufacturer label; On board reagent stability is 60 days. b. pocH pack L: Unopened stable to expiration date on manufacturer label; On board reagent stability is 90 days. 3. Staff interview with testing personnel #1 on 8/28/19 at 11:00 AM stated he/she was not aware of the change in expiration dates for the pack D and L reagents once they are placed into service. 4. The laboratory performs 2,593 CBC tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document routine maintenance and function checks for the Sysmex PocH-100i analyzer in the specialty of hematology. Findings include: 1. Record review of the Sysmex PocH-100i maintenance logs on 10/29/19 revealed the laboratory did not have documentation of maintenance and function checks for the following: a. Daily maintenance for 16 of 22 days January 2019. b. Daily, weekly and monthly maintenance for February, May, August and September 2019. c. 1 of 2 weeks cleaning of the transducer and 1 of 1 cleaning waste chamber for June 2019. d. 2 of 2 weeks cleaning of the transducer for July and October 2019. 2. Review of the manufacturer's operator manual for the above equipment on 10/29/19 revealed various maintenance protocols need to be performed on a daily, weekly, every 2 weeks, 3 months schedule in order to ensure accurate and reliable test results. 3. Staff interview with the technical consultant on 10/29/19 at 12: 05 PM confirmed the above findings. 4. The laboratory performs 2,593 Complete Blood Counts annually.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to perform and document calibration when a new Complete Blood Count (CBC) analyzer was placed in service to verify the accuracy of the test system in the specialty of hematology. Findings include: 1. Surveyor observation of the Sysmex PocH 100i Complete Blood Count (CBC) analyzer on 10/29/19 at 10:50 AM revealed an instrument serial number (S/N) of G4929. 2. Record review of calibration records on 10/29/19 revealed: a. Records were available for S/N B1111. b. The laboratory did not have calibration records for S/N G4929. 3. Staff interview with the technical consultant (TC) on 10/29/19 at 12:20 PM confirmed the above findings. The TC stated S/N G4929 was placed into service on 10/28/19 and the laboratory staff had only performed CBC controls prior to patient testing. 4. The laboratory performs 2,593 CBC tests annually.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's

	verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to take corrective action when the laboratory refrigerator temperatures were out of range. Findings include: 1. Surveyor observation of the laboratory refrigerator #1 contents on 10/29/19 at 11:45 AM revealed Sysmex Eightcheck-3WP X-tra Hematology controls, storage 2-8 Celsius (C). 2. Record review of the 2019 refrigerator temperature log on 10/29/19 revealed: a. Acceptable refrigerator temperature range 2 to 8 C. b. The laboratory did not have temperature documentation for 26 days in January and February. c. The laboratory did not have corrective action documented for 112 of 164 days from January through September when temperatures were outside the above range. 3. Staff interview with technical consultant on 10/29/19 at 12:00 PM confirmed temperatures were out of range on many occasions with no corrective action. 4. The laboratory performs 2,593 CBC tests annually.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 record review and staff interview, the laboratory director failed to ensure new testing personnel (TP) received appropriate training to perform moderate complexity testing prior to reporting patient test results. Findings include: 1. Record review of 2018 and 2019 TP employee files on 10/29/19 revealed the following: . a. 2 of 4 new TP did not have training documents completed and approved for complete blood counts (CBC) analyzed on the Sysmex PocH-100i instrument. b. 1 of 4 new TP hired 11/13/17 had training documents dated 10/25/19 for CBC testing with competency documents dated 11/13/17 and was signed by both the TP and technical consultant (TC). 2.. Staff interview with the TC on 10/29/19 at 9:30 AM confirmed the above findings. The TC stated the new TP have been performing and reporting patient test results. 3. Laboratory performs approximately 2,593 CBC tests annually.