Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 39D2151185	**(X3) Date Survey Completed** 10/04/2022
Name of Provider or Supplier Psh Holy Spirit Medical Ctr Poct	**Street Address, City, State** 503 N 21st Street, Camp Hill, 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**
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 review of the laboratory's Point of Care Testing Requirements Procedure and interview with Technical Consultants #3 and #4 (TC), the laboratory failed to establish a procedure that includes the six points of CLIA for the assessment of 118 of 118 testing personnel (TP) that performed point of care testing (POCT) in chemistry and hematology from 08/26/2020 to the date of survey. Findings include: 1. On the day of survey, 10/04/2022 at 12:05 pm, the TC could not provide a competency assessment policy that includes the minimum requirements of CLIA to assess 118 of 118 TP in 2020 and 2021 for the following: -i STAT ACTk (activated clotting time) -Avoximeter 1000e (CO-Oximetry) -epoc BGEM (blood gas, chloride, creatinine, glucose, hematocrit, ionized calcium, lactate, potassium, sodium) 2. The TC (TC#3) confirmed the finding above on 10/04/2020 around 03:00 pm.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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: Based on review of competency assessment records, and interview with Technical

	Consultants #3 and #4 (TC), , the TC failed to provide documentation of the direct observation of routine patient test performance, and handling and processing of patient specimens for 118 of 118 testing personnel that perform point of care testing (POCT) in chemistry and hematology from 08/26/2020 to the date of survey. Findings include: 1. On the day of survey, 10/04/2022 at 12:05 pm, the competency assessment records revealed the TC failed to document the direct observation of routine patient test performance, handling and processing of patient specimens for 118 of 118 TP in 2020 and 2021 for the following: -i STAT ACTk (activated clotting time) -Avoximeter 1000e (CO-Oximetry) -epoc BGEM (blood gas, chloride, creatinine, glucose, hematocrit, ionized calcium, lactate, potassium, sodium) 2. The TC (TC#3) confirmed the findings above on 10/04/2022 around 03:00 pm.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of competency assessment records, and interview with Technical Consultants #3 and #4 (TC), the TC failed to provide documentation of the direct observation of performance of instrument maintenance and function checks for 118 of 118 testing personnel (TP) that perform point of care testing (POCT) in chemistry and hematology from 08/26/2020 to the date of survey. Findings include: 1. On the day of survey, 10/04/2022 at 12:05 pm, the competency assessment records revealed the TC failed to document the direct observation of performance of instrument maintenance and function checks of 118 of 118 TP in 2020 and 2021 for the following: -i STAT ACTk (activated clotting time) -Avoximeter 1000e (CO-Oximetry) -epoc BGEM (blood gas, chloride, creatinine, glucose, hematocrit, ionized calcium, lactate, potassium, sodium) 2. The TC (TC#3) confirmed the findings above on 10/04/2022 around 03:00 pm.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of competency assessment records, and interview with Technical Consultants #3 and #4 (TC), the TC failed to evaluate the test performance of 118 of 118 testing personnel (TP) through internal blind testing or external proficiency testing (PT) samples for point of care testing (POCT) in chemistry and hematology from 08/26/2020 to the date of survey. Findings Include: 1. On the day of the survey, 10/04/2022 at 11:48 am, the competency assessment records revealed the laboratory did not evaluate the test performance of 118 of 118 TP through internal blind testing or external PT samples in 2020 and 2021 for the following: -i STAT ACTk (activated

	clotting time) -Avoximeter 1000e (CO-Oximetry) -epoc BGEM (blood gas, chloride, creatinine, glucose, hematocrit, ionized calcium, lactate, potassium, sodium) 2. The TC #3 confirmed the findings above on 10/04/2022 around 03:00 pm.