Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2172205	(X3) Date Survey Completed 03/15/2023
Name of Provider or Supplier Penn Medicine Lghp Uc-Norlanco	**Street Address, City, State** 432 Cloverleaf Road, Elizabethtown, 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 lack of documentation and interview with the Technical Consultant (TC) #1, The laboratory failed to performed the annual competency assessment of 1 of 1 Clinical Consultant (CC) and 2 of 2 Technical Consultants (TC) for their supervisory responsibilities in 2021 and 2022. Findings Include: 1. On the day of survey 03/15 /2023 at 10:40 am, the laboratory could not provide the annual competency assessment for 1 of 1 CC (CMS 209 personnel #2) and 2 of 2 TC (CMS 209 Personnel ## and #22) for their annual competency assessments in 2021 and 2022. 2. The TC#1 confirmed the finding above on 03/15/2023 at 01:00 pm.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the American Academy of Family Physicians (AAFP) and an interview with Technical Consultant (TC)#1, the laboratory failed to document the evaluation and verification activities for 6 of 6 PT testing performed in microbiology, chemistry, and hematology in 2021 and 2022. Findings Include: 1. On the day of the survey, 03/15/2023 at 11:30 am, a review of PT records revealed that the laboratory did not document the review for 3 of 3 AAFP PT result events in 2021 and 3 of 3

	AAFP PT result events in 2022 for the following test: - Potassium Hydroxide (mycology) - Wet preps (Parasitology) - Sodium (chemistry) - Potassium (chemistry) - Chloride (chemistry) - Ionized calcium (chemistry) - Glucose (chemistry) - Blood urea nitrogen (chemistry) - Creatinine (chemistry) - Total carbon dioxide (chemistry) - Hematocrit (Hematology) - Hemoglobin (Hematology 2. TC #1 confirmed the finding above on 03/15/2023 around 01:00 pm.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the procedure manual, lack of documentation and interview with the Technical Consultant(TC)#1, the Laboratory Director (LD) failed to ensure general laboratory Quality Assessment (QA) programs were maintained to ensure the quality of laboratory services provided from 03/31/2021 to 03/15/2023. Findings Include: 1. The Quality Management Plan procedure states the following: a. Page 1 under Overall Organization: "Each Medical Director and Technical Consultant is responsible for the development, implementation and evaluation of the quality program for their site. Quality indicators are implemented in all phases of the laboratory: pre-analytic, analytic, and post analytic". b. Page 1 under Definitions: "nonconforming activities can be identify in many different ways, including clinician complaints, quality control indicators, instrument calibrations, checking of consumable materials and staff reporting ". 2. On the day of survey 03/15/2023 at 12: 35 pm, TC#1 could not provide documentation of the periodic QA evaluation used by the laboratory to assess its preanalytical, analytical, and postanalytical processes for the following: - from 03/2021 to 12/31/2021: The laboratory did not provide the quarterly QA documentation that assess all the phases of the laboratory Chemistry, Hematology and Microbiology. - from 01/01/2022 to 12/31/2022: The laboratory did not provide the quarterly QA documentation that asses all phases for microbiology: Potassium Hydroxide (Mycology) and Wet Mounts (Parasitology). - from 01/02/2022 to 12/31/2023: the laboratory could not provide the quarterly QA documentation that assess the pre-analytic, and post-analytic phases of the IStat Chem8+ (Chemistry and Hematology) 3. TC#1 confirmed the findings above on 03/15/2023 at 01:00 p.m.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of competency assessment records, and interview with Technical Consultant (TC)#1, the technical consultant failed to

	evaluate and document the semi-annual Competency Assessment (CA) during the first year of employment for 2 of 21 Testing personnel (TP) responsible for performing Istat Chem 8 examinations from 03/31/2021 to 03/15/2023 Findings include: 1. The point of care testing trained staff procedure states (Page 1): "Employees performing any non- waived testing will also be evaluated using the 6 elements of competency, within 6 months of training and then annually thereafter." 2. On the day of the survey, 03/15/2023 at 11:10 am. the laboratory was unable to provide the semi-annual competency assessment records for 2 of 21 TP (CMS 209 personnel #7 and #22) who performed Istat Chem 8 examinations. - TP#7 initial training in the facility was on 02 /10/2021 - TP#22 initial training in the facility was on 08/10/2022 3. TC#1 confirmed the findings above on 03/15/2023 at 01:00 a.m.
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 laboratory procedures, review of competency assessment records, and interview with Technical Consultant (TC)#1, the technical consultant failed to evaluate and document the annual Competency Assessment (CA) for 2 of 21 Testing personnel (TP) responsible for performing Istat Chem 8 examinations in 2022. Findings include: 1. The point of care testing trained staff procedure states (Page 1): "Employees performing any non- waived testing will also be evaluated using the 6 elements of competency, within 6 months of training and the annually thereafter." 2. On the day of the survey, 03/15/2023 at 11:10 am. the laboratory was unable to provide the annual competency assessment records for 2 of 21 TP (CMS 209 personnel #6 and #7) who performed Istat Chem 8 examinations in 2022. 3. CMS 116- laboratory annual volume for Chemistry and Hematology is 179. 4. The TC#1 confirmed the findings above on 03/15/2023 at 01:00 pm.