Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2130205	(X3) Date Survey Completed 07/06/2023
Name of Provider or Supplier Patient First - Collegeville	**Street Address, City, State** 1411 S Collegeville Road, Collegeville, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor record review and interviews with the Director of Laboratory Services, Technical Consultants #1 and #2 (TC) (CMS 209 personnel #2, and #3), the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met for having a supervisor on site during all normal scheduled working hours in which tests are performed from 07/13/2021 to the date of survey. Findings include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. The laboratory director (LD) is listed as a General Supervisor (GS) on the Pennsylvania State Laboratory State Personnel Report form. 3. Review of the CMS-116 form signed by the laboratory director (LD) on 06/29/2023 states that the director of this laboratory serves as director for one additional laboratory that are separately certified. 4. On the day of survey 07/06/2023 at 10:34 am, during an interview, TC #1 stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing as required by the State of PA.
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 the competency assessment (CA) records and interviews with the Director of Laboratory Services, Technical Consultants #1 and #2 (TC) (CMS 209 personnel #2, and #3), the technical consultant (TC) failed to assess the 6-months competency for 1 of 2 testing personnel (TP) for microbiology, chemistry and hematology testing performed in 2022. Findings include: 1. On the day of the survey, 07/06/2023 at 10:25 am, the laboratory could not provide 6-months CA records for 1 of 2 TP (CMS 209 personnel #5) who performed microbiology (bacteriology, mycology and parasitology), chemistry (routine chemistry, urinalysis and endocrinology), and hematology examinations from 04/01/2022 to 07/06/2023. 2. TC #1, TC #2 and the Director of Laboratory Services, confirmed the findings above on 07/06/2023 around 12:00 pm.