Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0336123	04/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Premier Physicians Centers, Inc Lab	25200 Center Ridge Road, Ste 1500a, Westlake, OH	

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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Supervisor (TS) #2, the laboratory failed to meet the requirements for urine culture testing and reporting in the subspecialty of Bacteriology. All patient urine culture testing had the potential to be affected by this deficient practice. Findings Include: 1. The laboratory failed to follow the manufacturer's instructions for the incubation time of the Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) and inoculated 32 out of 32 patient urine cultures on a Saturday, incubated the agar for more than 24 hours and read/reported the urine culture results on the following Monday from January 1, 2019 through April 17, 2019. (Refer to D5411) 2. The laboratory failed to follow the manufacturer's instructions for the incubation temperature of the Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) and incubated patient urine cultures beyond the manufacturer's requirements in 2018 and 2019. (Refer to D5413) 3. The laboratory failed to check each batch (lot number and shipment) of Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) for their ability to support growth, inhibit specific organisms and produce a biochemical response in 2017, 2018 and 2019. All patient urine culture testing and reporting had the potential to be affected by this deficient practice. (Refer to D5477) 4. The laboratory failed to review the effectiveness of their analytic systems' quality assessment program. All patients had the potential to be affected by this deficient practice. (Refer to D5793)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)

	Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Supervisor (TS) #2, the laboratory failed to follow the manufacturer's instructions for the incubation time of the Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) and inoculated 32 out of 32 patient urine cultures on a Saturday, incubated the agar for more than 24 hours and read/reported the urine culture results on the following Monday from January 1, 2019 through April 17, 2019. Findings Include: 1. Review of the manufacturer's package instructions found the following statements: BBL Trypticase Soy Agar with 5% Sheep Blood (TSA II) "Procedure... Incubate plates...for 18-24 h." BBL MacConkey II Agar "Procedure... Incubate plates...for 18-24 h." h; hour(s) 2. Review of the laboratory's "Microbiology Urine Culture" policy and procedure approved, signed and dated by the Laboratory Director on 03/25/2019 found the following statements: a. "...incubate for at least 24 hours." b. "After 24 hours of incubation observe the plates for any growth." 3. Review of the laboratory's 2019 urine culture log sheet found 32 out of 32 patient specimens read beyond the manufacturer's instructions of 24 hours in which the specimens were inoculated on a Saturday and read/reported on the following Monday as listed below: Patient Inoculated Read/Reported 1-XXXX98 01/05/2019 01/07/2019 1-XXXX43 01/19 /2019 01/21/2019 1-XXXX10 01/19/2019 01/21/2019 1-XXXX84 01/26/2019 01/28 /2019 1-XXXX03 02/02/2019 02/04/2019 1-XXXX71 02/09/2019 02/11/2019 1-XXXX51 02/09/2019 02/11/2019 1-XXXX57 02/16/2019 02/18/2019 1-XXXX43 02 /16/2019 02/18/2019 1-XXXX88 02/16/2019 02/18/2019 1-XXXX93 02/16/2019 02 /18/2019 2-XXXX25 02/16/2019 02/18/2019 2-XXXX77 02/16/2019 02/18/2019 1-XXXX33 02/16/2019 02/18/2019 2-XXXX99 02/23/2019 02/25/2019 1-XXXX06 02 /23/2019 02/25/2019 1-XXXX18 02/23/2019 02/25/2019 1-XXXX92 03/02/2019 03 /04/2019 1-XXXX57 03/02/2019 03/04/2019 1-XXXX88 03/02/2019 03/04/2019 1-XXXX83 03/02/2019 03/04/2019 1-XXXX25 03/16/2019 03/18/2019 1-XXXX58 03 /16/2019 03/18/2019 1-XXXX74 03/16/2019 03/18/2019 1-XXXX39 03/30/2019 04 /01/2019 1-XXXX40 03/30/2019 04/01/2019 1-XXXX01 03/30/2019 04/01/2019 1-XXXX68 03/30/2019 04/01/2019 1-XXXX37 03/30/2019 04/01/2019 1-XXXX85 04 /06/2019 04/08/2019 1-XXXX90 04/06/2019 04/08/2019 2-XXXX88 04/06/2019 04 /08/2019 4. The OM and TS#2 confirmed that the laboratory did not follow the manufacturer's instructions and read/reported inoculated urine culture TSA and Mac plates after more than 24 hours of incubation. The interviews occurred on 04/17/2019 at 12:22 PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Supervisor (TS) #2, the laboratory failed to follow the manufacturer's instructions for the incubation temperature of the Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) and incubated patient urine cultures beyond the manufacturer's requirements in 2018 and 2019. All patient urine culture testing had the potential to be affected by this deficient practice. Findings Include: 1. Review of the manufacturer's package instructions found the following statements: BBL Trypticase Soy Agar with 5% Sheep Blood (TSA II) "Procedure... Incubate plates...at 35 +/- 2 C..." BBL MacConkey II Agar "Procedure... Incubate plates...at 35 +/- 2 C..." C; degrees Celsius 2. Review of the laboratory's "Microbiology Urine Culture" policy and procedure approved, signed and dated by the Laboratory Director on 03/25/2019 found the following statements: a. "...incubating in the microbiology incubator at 36 C..." b. "...incubated at 35-38 deg..." c. "Temps monitored/recorded daily (35-38 C)." deg; degrees Celsius 3. Review of the laboratory's 2018 and 2019 urine culture incubator temperature log sheet found the following number of days in each month when the incubator temperature was not within the manufacturer's instructions: Month/Year number of days incubator temp was not within the manufacturer's instructions 01/2018 21 out of 26 days 02/2018 13 out of 24 days 03/2018 12 out of 27 days 04/2018 15 out of 25 days 05/2018 6 out of 25 days 06/2018 11 out of 26 days 07/2018 15 out of 25 days 08 /2018 7 out of 27 days 09/2018 6 out of 23 days 10/2018 11 out of 27 days 11/2018 12 out of 23 days 12/2018 10 out of 25 days 01/2019 12 out of 26 days 02/2019 9 out of 24 days 03/2019 12 out of 26 days 04/2019 9 out of 15 days 4. The OM and TS#2 confirmed that the laboratory did not follow the manufacturer's instructions and incubated the TSA and Mac urine culture plates higher than 37 C. The interviews occurred on 04/17/2019 at 12:22 PM.
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 record review and interviews with the Office Manager (OM) and Technical Supervisor (TS) #2, the laboratory failed to check each batch (lot number and shipment) of Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) for their ability to support growth, inhibit specific organisms and produce a biochemical response in 2017, 2018 and 2019. All patient urine culture testing and reporting had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Microbiology Urine Culture" policy and procedure, approved, signed and dated by the Laboratory Director on 03/28/2019 and provided on the date of the inspection found a section titled "VII. Quality Control-IQCP" consisting of the bulleted sub-sections; "Risk Assessment" and "QC Plan". The "QC Plan" sub-section did not indicate any onsite QC activities other than visual inspections, sterility checks

	and printing of the BD Quality Certificate of Analysis from the BD website. IQCP; Individualized Quality Control Plan QC; quality control 2. Further review of the laboratory's IQCP documentation did not find any historical or current QC activity recorded for the TSA and Mac urine culture plates consisting of testing specific organisms to show the agar supported growth, inhibited specific organisms and produced a biochemical response, as applicable, for each batch (lot number and shipment) received. Additionally, there was no mention of incorporating the IQCP into the quality assessment program. 3. The OM and TS#2 confirmed via an email and a phone conversation on 04/29/2019 at 2:30 PM that the laboratory had not conducted any TSA and Mac QC activities to include testing specific organisms to show the agar supported growth, inhibited specific organisms and produced a biochemical response, as applicable, for each batch (lot number and shipment) received.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Supervisor (TS) #2, the laboratory failed to review the effectiveness of their analytic systems' quality assessment program. All patients had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Premier Physicians Quality Assurance Plan" policy and procedure, provided on the date of the inspection, did not find instructions to assess the effectiveness of their quality assessment program. 2. Review of the laboratory's 2017, 2018 and 2019 quality assessment documentation, provided on the date of the inspection, found a "Monthly QA Checklist" completed for each month, however did not find any indication of any problems in the analytic systems as identified during the onsite CLIA inspection regarding unacceptable urine culture incubation temperatures and length of incubation time according to the manufacturer's instructions and the lack of media quality control to check each batch (lot number and shipment) of Trypticase Soy Agar (TSA) and MacConkey Agar (Mac) for their ability to support growth, inhibit specific organisms and produce a biochemical response in 2017, 2018 and 2019. 3. The OM confirmed the laboratory's 2017, 2018 and 2019 quality assessment documentation, provided on the date of the inspection, did not effectively indicate the problems identified during the onsite CLIA inspection. The interview occurred on 04/17/2019 at 12:22 PM.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical

	Supervisor (TS) #2, the TS failed to provide technical supervision to evaluate the competency of Testing Personnel (TP) #1 to assure they maintained their competency to perform moderate and high complexity test procedures and report accurate test results. All patient testing performed by TP#1 had the potential to be affected by this deficient practice. Findings Include: 1. The TS failed to evaluate the competency of TP#1 to assure they maintained their competency to perform moderate and high complexity test procedures and report test results promptly, accurately, and proficiently in 2017, 2018 and 2019. All patient testing performed by TP#1 had the potential to be affected by this deficient practice. (Refer to D6120)
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM) and Technical Supervisor (TS) #2, the TS failed to evaluate the competency of testing personnel (TP) #1 to assure they maintained their competency to perform moderate and high complexity test procedures and report test results promptly, accurately, and proficiently in 2017, 2018 and 2019. All patient testing performed by TP#1 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's Form CMS-209 revealed one out of six individuals listed as Testing Personnel (TP) who was also listed as a TS and General Supervisor (GS). In addition, the OM was listed as a TS and GS. Both TS and GS individuals were qualified and credentialed by the Laboratory Director, via signature and date on 04/15/2019, to perform the functions and responsibilities of each position. 2. Review of the laboratory's "Competency Assessment" policy and procedure found the following statements: "...the laboratory director, technical consultant, site coordinator, or other designated person must critically observe the individual being checked to determine that procedural methods and protocols are followed correctly, proper technique is used in the performance of the assay, and safety guidelines are followed." "The evaluator, usually the site coordinator, will directly observe the entire testing procedure..." 3. Review of the laboratory's 2017, 2018 and 2019 competency assessment documentation, provided on the date of the inspection, revealed the assessment of TP#1's competency was not conducted by a qualified, listed and/or delegated TS or GS for moderate and/or high complexity testing procedures. TP#1 2017 assessed by TP#4 and TP#6 2018 assessed by TP#4 and TP#6 2019 no competency assessments completed 4. Review of the education documentation for TP#4 and TP#6, provided on the date of the inspection, revealed the following degrees achieved: TP#4; Associates of Applied Science Clinical Laboratory Science Technology TP#6; Associates of Applied Science Medical Laboratory Technician 5. The OM and TS#2 confirmed the laboratory's 2017 and 2018 competency assessments for TP#1 were not conducted by a qualified, listed and/or delegated TS or GS. The interviews occurred on 04/17/2019 at 9:45 AM.