Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0336020	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Uhmp Partners In Pediatrics	960 Clague Road Suite 1850, 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 Quality Assurance & Lab Administrator (QA&LA), the Practice Lead (PL) and the Practice Supervisor (PS), the laboratory failed to meet the requirements for throat culture testing and reporting in the subspecialty of Bacteriology. This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported. Findings Include: 1. The laboratory failed to follow the manufacturer's result reporting instructions for the BD (Becton Dickinson) BBL Taxo Discs for Differentiation of Group A Streptococci (Strep). This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported from 06/12/2019 to the date of the validation inspection. (Refer to D5411) 2. The laboratory failed to demonstrate performance specifications as established by the manufacturer for accuracy, precision, reportable range and reference intervals, prior to reporting patient test results, utilizing the newly implemented Hardy Diagnostics Group A Beta Streptococcus (Strep) Agar plates for throat culture testing that began on 06/12/2019. This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported from 06/12 /2019 to the date of the validation inspection. (Refer to D5421) 3. The laboratory failed to determine and indicate, in their Individualized Quality Control Plan (IQCP), the type, number and frequency of quality control (QC) testing of the Group A Beta Streptococcus (Strep) Agar plates that were utilized for patient throat culture testing. This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported from 06/12/2019 to the date of the validation inspection. (Refer to D5425)

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 Quality Assurance & Lab Administrator (QA&LA), the Practice Lead (PL) and the Practice Supervisor (PS), the laboratory failed to follow the manufacturer's result reporting instructions for the BD (Becton Dickinson) BBL Taxo Discs for Differentiation of Group A Streptococci (Strep). This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported from 06/12/2019 to the date of the validation inspection. Findings Include: 1. Review of the BD BBL Taxo Discs for Differentiation of Group A Strep manufacturer's instructions revealed the following result reporting instructions: "Results A zone of inhibition is formed around the Taxo disc if the organism is a group A streptococcus. It is recommended that any zone of inhibition, regardless of diameter, be reported as 'beta-hemolytic Streptococcus, presumptively group A by bacitracin'. No zone of inhibition (growth up to the edge of the disc) is reported as 'beta-hemolytic Streptococcus, presumptively not group A by bacitracin'. Limitations of the Procedure The Taxo A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." 2. Review of the laboratory's "Back-Up Strep Procedure" policy and procedure, approved, signed and dated by the Laboratory Director on 02/07/2018 and 02/15/2019 and provided on the date of the validation inspection, found the following result reporting instructions: "...The control (and patient) will be considered positive if a zone of inhibition around the Taxo A disc is seen. ...The control (and patient) will be considered negative if growth is observed up to the taxo A disc and a zone of inhibition is not evident." 3. Review of the laboratory's "UHMSO-CLIN-19.0-IQCP Policy for Microbiology" policy and procedure, approved, signed and dated by the Laboratory Director on 11/01/2018 and 01/08/2019 and provided on the date of the validation inspection, did not find any mention of performance specification activities and result reporting instructions. 4. Review of 340 out of 340 of the laboratory's 2019 patient test records utilizing the newly implemented Group A Beta Strep Agar found throat culture results documented as "neg" or "pos". One out of one corresponding 2019 patient test record and final test report dated 06/24/2019 found the following result: "Patient Strep Log 2019" test record; "Back up Plate 24 hr result"; "neg" Final test report "IO Back Up Rapid Strep Culture 24 hours"; "Negative" neg; negative pos; positive hr; hour IO; in house 5. The QA&LA and the PL confirmed that the laboratory had not conducted any performance specification activities, did not follow the manufacturer's result reporting instructions and reported the throat culture results as "neg/negative" or "pos/positive" in the test records and on the final test report respectively. The interviews occurred on 10/17/2019 at 12:20 PM.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interviews with the Quality Assurance & Lab Administrator (QA&LA), the Practice Lead (PL) and the Practice Supervisor (PS), the laboratory failed to demonstrate performance specifications as established by the manufacturer for accuracy, precision, reportable range and reference intervals, prior to reporting patient test results, utilizing the newly implemented Hardy Diagnostics Group A Beta Streptococcus (Strep) Agar plates for throat culture testing that began on 06/12/2019. This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported from 06/12/2019 to the date of the validation inspection. Findings Include: 1. Review of the laboratory's policies and procedures provided on the date of the validation inspection did not find any mention of a performance specification policy and procedure. 2. The Inspector requested the laboratory's approved performance specification policy and procedure and all corresponding 2019 performance specification documentation for the newly implemented Hardy Diagnostics Group A Beta Strep Agar plates for throat culture testing from the QA&LA, the PL and the PS. The QA&LA and PL confirmed, on 10/17/2019 at 11:45 AM and via a telephone conference call on 10/22/2019 at 9:35 AM, that the laboratory did not establish a performance verification policy and procedure, did not conduct any performance verification activities of the newly implemented Hardy Diagnostics Group A Beta Strep Agar plates utilized for patient throat culture testing and were unable to provide the requested documentation.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 Quality Assurance & Lab Administrator (QA&LA), the Practice Lead (PL) and the Practice Supervisor (PS), the laboratory failed to perform and document any quality control (QC) procedures using the number and frequency specified by the manufacturer or established by the laboratory in their Individualized Quality Control Plan (IQCP) for the Group A Beta Streptococcus (Strep) Agar plates. This deficient practice had the potential to affect 340 out of 340 patient throat cultures tested and reported from 06/12/2019 to the date of the validation inspection. Findings Include: 1. Review of the laboratory's "UHMSO-CLIN-19.0-IQCP Policy for Microbiology" policy and procedure, approved, signed and dated by the Laboratory Director on 11/01/2018 and 01/08/2019 and provided on the date of the validation inspection, did not find any historical QC data or

	instructions for the type, number and frequency of QC testing of the Group A Beta Strep Agar plates; however, revealed the following statements: "All shipments and lots of plates...are accompanied by manufacturer's documentation that Quality Control was run at factory...place the proof of quality control sticker on the appropriate log... plate...placed in the incubator without inoculation as a sterility test. Each lot and/or shipment will also be checked for visible contamination, cracks or abnormal discoloration." "...We have used Proficiency testing and random additional Quality Control testing...as proof that all UHMP offices have produced correct results and meet the IQCP criteria." 2. Review of the laboratory's "Back-Up Strep Procedure" policy and procedure, approved, signed and dated by the Laboratory Director on 02/07 /2018 and 02/15/2019 and provided on the date of the validation inspection, did not find any instructions for the type, number and frequency of QC testing of the Group A Beta Strep Agar plates; however, revealed the following statements: "As needed QC: All plates must be inspected upon receipt and before use for cracks or discoloration..." 1. Sterility test: For this control place an unopened strep plate in the incubator and check for growth, drying, cracking and or abnormal discoloration...This must be performed...each shipment and/or lot of plate received." 2. Plate Quality Control... remove the label from each stack of plates as you open them for use. Place this label on the Plate Quality Control sheet..." 3. Bacitracin Disc (Taxo A) Quality Control... run a positive and negative control before you put a new lot and/or shipment into use..." "...Positive control: Plate a strep plate using Streptococcus Pyogenes control swab or Previously Graded Proficiency Test. Place Taxo A disc in the initial inoculum area of the plate. This checks the plate, the Taxo disc and the tech's technique. The control must be positive...The control (and patient) will be considered positive if a zone of inhibition around the Taxo A disc is seen. Negative control: Plate a strep plate using Streptococcus Group B swab or Previously Graded Proficiency Test. Place Taxo A disc in the initial inoculum area of the plate. This checks the plate, the Taxo disc and the tech's technique. The control must be negative...The control (and patient) will be considered negative if growth is observed up to the taxo A disc and a zone of inhibition is not evident." 3. The Inspector requested the laboratory's historical QC records for each shipment and lot number of Group A Beta Strep Agar plates utilized in the laboratory's IQCP Risk Assessment (RA) as well as the laboratory's Quality Control Plan (QCP) QC records from the QA&LA, the PL and the PS. The QA&LA and PL provided the laboratory's 2018 and 2019 "Quality Control Log for Strep Plates" worksheets which indicated the following column labeling: Date, time and initials of set-up and read Strep Plate lot number and expiration date Taxo A disc lot number and expiration date Group A positive QC sample identity Group B negative QC sample identity Sterility Plate QC results Positive QC results Negative QC results Further review of the laboratory's "Quality Control Log for Strep Plates" worksheets did not find any historical QC activities performed and documented for each shipment and lot number of Group A Beta Strep Agar plates and revealed only positive and negative QC activities were recorded for each shipment and lot number of Bacitracin (Taxo A) discs with the lot number of Group A Beta Strep Agar plates in use at the time. 4. The QA&LA and the PL confirmed that the laboratory did not conduct, document and include any QC testing of each shipment and lot number of the Group A Beta Strep Agar plates utilized in their IQCP RA as historical data to show a stable test system for patient throat culture testing, the laboratory's IQCP did not indicate the type, number and frequency of QC testing of the Group A Beta Strep Agar plates and the laboratory did not routinely perform anything other than a sterility check and visual inspection on each shipment and lot number of the Group A Beta Strep Agar plates. The interviews occurred on 10/17/2019 at 11:45 AM and via a telephone conference call on 10/22/2019 at 9:35 AM.