Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1025920	05/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
William Van Bingham Md Pc	6005 Park Avenue, Suite 803, Memphis, TN	

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 procedure manual, the form used for documenting testing personnel training and competency, and interview with the laboratory liaison, the laboratory failed to have a procedure that included all six criteria for assessing personnel competency in 2017, 2018, and 2019. The findings include: 1) Review of the laboratory procedure manual revealed no procedure for testing personnel competency assessment. The following six criteria were not included in the procedure manual: direct observation of routine patient test performance; monitoring the recording and reporting of test results; review of intermediate test results or worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of performance of instrument maintenance and function checks; assessment of test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2) Review of the form used for documenting testing personnel training and competency revealed that direct observation of patient testing, monitoring the recording and reporting of test results, record review including intermediate test results, worksheets, quality control records, proficiency testing results and preventative maintenance records; direct observation of maintenance and function checks, blind testing, and problem solving were not included on the form. 3) Interview with the laboratory liaison May 29, 2019 at 11:30 am confirmed the laboratory procedure manual did not include a policy for assessing testing personnel

	competency. The checklist used for documenting training and competency did not include the six criteria for testing personnel competency assessment required by the Centers for Medicare and Medicaid Services (CMS).
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records, the laboratory's proficiency testing program reports and interview with the laboratory liaison, the laboratory failed to verify the accuracy of urine microscopy twice a year in 2018. The findings include: 1) Review of the laboratory proficiency testing records revealed enrollment in proficiency for urine microscopy. Performance evaluation reports were not available for 2018 events one and three; and the laboratory scored a 50% for urine microscopy for 2018 event two. 2) Review of the laboratory's proficiency testing program performance summary report obtained from the laboratory's proficiency testing provider revealed a score of 50% for 2018 events two and three for urine microscopy. 3) Interview with the laboratory liaison on May 29, 2019 at 11:30 am confirmed the laboratory enrolls in proficiency testing for verification of accuracy of urine microscopy procedures. No records were available for 2018 events one and three, and the laboratory scored 50% for 2018 event two. The laboratory failed to verify the accuracy of urine microscopy twice a year in 2018.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: The laboratory director failed to ensure compliance with regulations (Refer to D6004), failed to ensure proficiency testing reports were available and reviewed (Refer to D6018), failed to ensure the proficiency testing corrective action plan was followed for unacceptable proficiency testing (Refer to D6019), failed to ensure quality assessment programs are maintained (Refer to D6021), failed to ensure documentation of testing personnel education (Refer to D6029) and failed to ensure job descriptions were present for all laboratory positions (Refer to D6032).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel

	meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services (CMS) Laboratory Personnel Report (form CMS-209), the CMS Aspen database, Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (form CMS-116), the laboratory procedure manual, and interview with the laboratory liaison, the laboratory director failed to ensure CLIA compliance when the CLIA program was not notified of the change in laboratory director within 30 days of the change, and the change in specialties within six months. The findings include: 1) Review of the form CMS-209 with comparison to the CMS Aspen database revealed the name of a laboratory director on the CMS-209 that was different from the CMS Aspen database. 2) Review of the Aspen database with comparison to the CMS-116 form revealed discrepancies for the laboratory specialties of histopathology and cytology. The Aspen database revealed laboratory testing in the specialties of histopathology and cytology; the CMS-116 form revealed the laboratory was no longer performing testing in the specialties of histopathology and cytology. There was no documentation in the Aspen database that the CLIA program had been notified of the change in laboratory director and change in specialties. 3) Review of the laboratory procedure manual revealed a policy in place with appropriate notification requirements. 4) Interview with the laboratory liaison on May 29, 2019 at 11:30 am confirmed the laboratory director failed to ensure CLIA compliance when the CLIA program was not notified of the change in laboratory director and change in specialties in 2018. The laboratory director changed August 2018 and the laboratory stopped performing testing for histopathology and cytology in July 2018.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing records and interview with the laboratory liaison, the laboratory director failed to ensure proficiency testing results were available and reviewed in 2017, 2018, and 2019. The findings include: 1) Review of the laboratory proficiency testing records revealed no performance evaluation reports were available for review for urine microscopy and post-vas semen analysis for 2017 event 2, 2018 event 1, 2018 event 3, and 2019 event 1. 2) Interview with the laboratory liaison on May 29, 2019 at 11:30 am confirmed the laboratory director failed to ensure proficiency testing results were available and reviewed in 2017, 2018 and 2019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, proficiency testing records and interview with the laboratory liaison, the laboratory director failed to ensure the proficiency testing corrective action plan was followed for unacceptable proficiency testing results in 2017 and 2018. The findings include: 1) Review of the laboratory procedure titled "LABORATORY PROFICIENCY TESTING" revealed the following: "Corrective action will be undertaken and documented whenever unsatisfactory participation is identified. Corrective action to include re-training of staff members by the Laboratory Director to correct the problems associated with the proficiency testing failure." "Any time a score of less than 100% is received, a corrective action report will be completed. The corrective action report will be signed and dated by the testing personnel and the Laboratory Director." 2) Review of the laboratory proficiency testing records revealed the following for urine microscopy: 2017 Event 3 sample numbers US-05 and US-06 both scored as unacceptable with no documented retraining of testing personnel or corrective action. 2018 Event 2 sample number US-04 scored as unacceptable with no documented retraining of testing personnel or corrective action. 3) Interview with the laboratory liaison on May 29, 2019 at 11:30 am confirmed the laboratory director failed to ensure the corrective action plan for unacceptable proficiency testing results was followed in 2017 and 2018.
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 laboratory procedure manual, the log used for documenting weekly urine microscopy quality assessments, and interview with the laboratory liaison, the laboratory director failed to ensure the weekly quality assessment for the microscopic urinalysis was maintained in 2019. The findings include: 1) Review of the laboratory procedure titled "Microscopic Urinalysis Controls" revealed the following: "There will be a weekly review of one randomly chosen microscopic result." "Results in the EMR will be compared to the print-out for accuracy." The Laboratory Director will review logs quarterly to ensure that this system is sufficient to prevent any reporting errors. 2) Review of the log titled "Microscopy Monitoring", labeled Year 2019, revealed no documentation of weekly checks, and no review by

	the laboratory director. 3) Interview with the laboratory liaison on May 29, 2019 at 11: 30 am confirmed the laboratory director failed to ensure the weekly urine microscopic quality assessment was maintained January 2019 to current date.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the Center for Medicare and Medicaid Services Personnel Report form (CMS-209), testing personnel records, and interview with the laboratory liaison, the laboratory director failed to ensure testing personnel number one had the appropriate education prior to patient testing in 2017. The findings include: 1) Review of the CMS-209 form revealed the name of testing personnel number one. 2) Review of the testing personnel records revealed no documentation of education for testing personnel number one. Date of hire listed on the form was 09.06.2017. 3) Interview with the laboratory liaison on May 29, 2019 at 11:30 am confirmed the laboratory director failed to ensure testing personnel number one had appropriate documentation of education prior to patient testing. Testing personnel number one began patient testing for urine microscopy and post vas semen analysis in September 2017 and the personnel records did not contain any documentation of education.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual and interview with the laboratory liaison, the laboratory director failed to ensure job descriptions were present that outlined the duties and responsibilities of the laboratory director, technical consultant, and clinical consultant. The findings include: 1) Review of the laboratory procedure manual revealed no job descriptions were present for the laboratory director, technical consultant, and clinical consultant. 2) Interview with the laboratory liaison on May 29,

	2019 at 11:30 am confirmed the laboratory director failed to ensure job descriptions were present for the laboratory director, technical consultant, and clinical consultant.