Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0225176	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier Winchester Internal Medicine, Inc	**Street Address, City, State** 190 Campus Boulevard - Suite 200, Winchester, VA	
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
D0000	An announced CLIA validation survey was conducted at Winchester Internal Medicine on February 26, 2025 the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), policy and procedure manual, personnel records, and interview, the laboratory did not establish and follow a policy for one (1) of 1 technical supervisor (TS) and 1 of 1 general supervisor (GS) competency assessments from January 2023 until December 2024. The findings include: 1. Review of the CMS 209 revealed the laboratory director (LD) identified Testing Personnel (TP) A as the TS and GS for the specialties of Chemistry and Hematology. (See Personnel Code Sheet.) 2. Review of the laboratory policy and procedure manual revealed a lack of a policy outlining the documentation of the competency assessment of laboratory personnel in the roles of TS and GS. 3. Review of the laboratory's personnel records revealed the LD failed to document the competency assessments for TP A in the roles of TS and GS from January 2023 until December 2024. The surveyor requested to review the competency assessments for TP A in the roles of TS and GS. The laboratory provided no documentation for review. In an interview with TPA (TS & GS) on February 26, 2025, at 9:15 AM, TP A stated the laboratory did not have a policy for TS & GS competencies until cited by their accrediting agency. TP A provided a copy of the competency policy dated and signed by the LD on 12/23/2024.

	4. In an interview with the TS on February 26, 2025 at 1:00 PM, the above findings were confirmed.
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 proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to document remedial action taken for one (1) of five (5) High Density Lipoprotein (HDL) challenges tested in the American Proficiency Institute 2024 Chemistry Event 1. Review timeframe January 2023 until February 2025. The findings include: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2024 Chemistry Event 1 revealed a HDL CH-05 sample scored as unacceptable. Challenges CH-01 to CH-04 were scored as acceptable. Further review of the event revealed a lack of evidence of remedial action taken for the unsatisfactorily scored HDL CH-05 challenge. 2. Review of available PT records from January 2024 until February 2025 revealed no remedial or verification action documented for the unsatisfactory HDL CH-05 score outlined above. 3. In an interview with the TS on February 26, 2025 at 1:00 PM, the above findings were confirmed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's policy and procedure manual, lack of documentation and interviews, the laboratory failed to establish a written policy for the performance of manual White Blood Cell (WBC) differentials from January 2023 until December 2024. The findings include: 1. During a tour of the laboratory on February 26, 2025, at 8:30 AM, the surveyor noted a microscope, manual differential counter and manual staining jars. The surveyor asked the Technical Supervisor (TS) if they perform manual WBC differentials. The Technical Supervisor responded they only perform manual differentials when alerted by the Sysmex XN-530 Hematology Analyzer. The TS wasn't sure when they began performing manual differentials but were performing before the last accrediting inspection in October 2023. 2. Review of the laboratory's policy and procedure manual revealed the laboratory had a manual differential procedure signed and dated by the laboratory director on 12/18/2024. The surveyor requested to review a written manual WBC differential procedure prior to December 2024. The laboratory provided no procedure for review. In an interview with the TS on February 26, 2025, at 11:00 AM, the TS stated the laboratory did not have a procedure prior to December 2024. 3. In an interview with the TS on February 26, 2025 at 1:00 PM, the above findings were confirmed.

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory policies and procedures, personnel records, competency documentation, lack of documentation and interviews, the laboratory director failed to delegate and ensure competency assessments were performed by personnel qualified to perform competencies from January 2023 until December 2024. The findings include: 1. Review of the CMS 209 revealed the laboratory director (LD) identified Testing Personnel (TP) A as the technical supervisor (TS) and general supervisor (GS) for the specialties of Chemistry and Hematology. (See Personnel Code Sheet.) 2. Review of TP A's (TS/GS) personnel records revealed a lack of documentation of the LD's delegation of the performance of laboratory's competency assessments to TP A. 3. Review of the laboratory's competency records revealed TP A (TS/GS) performed competency assessments for TP B, C and D. Further review of the laboratory's competency assessments revealed TP A's Chemistry and Hematology competency assessments for 2023 and 2024 were performed by TP B. 4. Review of TP B's personnel records revealed TP B was a high school graduate with no further education. The surveyor requested to review additional education documents. The laboratory provided no additional documentation. In an interview with TP A (TS/GS) on February 26, 2025, at 9:30 AM, TP A stated they did not realize TP B could not perform their competencies until their recent accrediting inspection in December 2024. 5. In an exit interview with the TS/GS on February 26, 2025 at 1:00 PM, the above findings were confirmed.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: A. Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, laboratory policies and procedures and interviews, the laboratory director (LD) failed to ensure the establishment of a policy for the

	performance of competency assessments of testing personnel (TP) on a semi-annual basis for two (2) of 2 newly hired TP performing Chemistry and Hematology testing from January 2023 until December 2024. The findings include: 1. Review of the laboratory's CMS 209 form revealed the LD listed four TP performing Chemistry and Hematology testing. In an interview with the Technical Supervisor (TS) on February 26, 2025 at 9:15 AM, the TS stated TP C was hired/trained in March 2023 and TP D was hired/trained in July 2022 (see Personnel Code Sheet). 2. Review of the laboratory's personnel records revealed a lack of documentation of semi-annual competency assessments for TP C and TP D during their first year of patient testing. The surveyor requested documentation of the semi-annual competency assessments for TP C and D. The laboratory provided no documentation for review. 3. Review of the laboratory policy and procedure manual revealed a lack of a policy outlining the documentation of the semi-annual competency assessment for newly hired laboratory personnel. In an interview with the TS on February 26, 2025, at 9:15 AM, the TS stated the laboratory did not have a policy for semi-annual competencies until cited by their accrediting agency. The TS provided a copy of the competency policy signed and dated by the LD on 12/16/2024. 4. In an exit interview with the TS on February 26, 2025 at 1:00 PM, the findings were confirmed. B. Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, laboratory policies and procedures and interviews, the laboratory director (LD) failed to ensure the establishment of a policy for the performance of competency assessment of testing personnel (TP) performing manual White Blood Cell (WBC) differentials for four (4) of 4 TP performing manual WBC differentials from January 2023 until December 2024. The findings include: 1. Review of the laboratory's CMS 209 form revealed the LD listed four TP performing Hematology testing. In an interview with the Technical Supervisor (TS) on February 26, 2025, at 9:15 AM, the TS stated TP A, B, C, and D perform manual WBC differentials (see Personnel Code Sheet). 2. Review of the laboratory's competency records revealed a lack of documentation of the following manual WBC differential competency assessments: Annual competency assessments for 2023 and 2024 for TP A, B, C and D. Semi-annual competency assessments for TP C and D (see D6103 A. for details). The surveyor requested documentation of the manual WBC differential competency assessments for the above listed testing personnel. The laboratory provided no documentation for review. 3. Review of the laboratory policy and procedure manual revealed a lack of a policy outlining the documentation of the manual WBC differential competency assessments. In an interview with the TS on February 26, 2025, at 9:15 AM, the TS stated the laboratory did not have a policy and had not performed differential competencies until cited by their accrediting agency. The TS provided a copy of the competency policy signed and dated by the LD on 12/16/2024. 4. In an exit interview with the TS on February 26, 2025 at 1:00 PM, the findings were confirmed.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), personnel records, laboratory policies and procedures and interviews, the technical supervisor (TS) failed to perform semi-annual competency assessments for two (2) of

	2 newly hired TP performing Chemistry and Hematology testing from January 2023 until the date of the survey on February 26, 2025. The findings include: 1. Review of the laboratory's CMS 209 form revealed the LD listed four TP performing Chemistry and Hematology testing. In an interview with the Technical Supervisor (TS) on February 26, 2025, at 9:15 AM, the TS stated TP C was hired/trained in March 2023 and TP D was hired/trained in July 2022 (see Personnel Code Sheet). 2. Review of the laboratory's personnel records revealed a lack of documentation of of the semi-annual competency assessments for TP C and TP D during their first year of patient testing. The surveyor requested documentation of the semi-annual competency assessments for TP C and D. The laboratory provided no documentation for review. 3. Review of the laboratory policy and procedure manual revealed a lack of a policy outlining the documentation of the semi-annual competency assessment for newly hired laboratory personnel. In an interview with the TS on February 26, 2025, at 9:15 AM, the TS stated the laboratory did not have a policy for semi-annual competencies until cited by their accrediting agency. The TS provided a copy of the competency policy signed and dated by the LD on 12/16/2024. 4. In an exit interview with the TS on February 26, 2025 at 1:00 PM, the findings were confirmed.