Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2334696	04/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Vitalskin Medical Group Il, Pllc	1111 West Kenyon Rd - Suite C, Urbana, IL	

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
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to establish and follow written policies and procedures to assess seven of seven TP competencies (see D5209), failed to document the check of positive and negative reactivity of immunohistochemical stains each time of use for three of three histopathology patients reviewed (see D5601a) and to document a control slide of known reactivity of special stains with each patient slide or group of patient slides for three of three histopathology patients reviewed (see D5601b), and failed to perform corrective actions for out of range temperature and humidity readings that did not meet the laboratory's established performance specifications for four of four testing dates reviewed affecting patient testing in the subspecialty of histopathology from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026 (see D5781).
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 CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to establish and follow written policies and procedures to assess seven of seven TP competencies in the subspecialty of histopathology. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form, signed by the laboratory director on 04/15/2026, revealed seven TP (TP #2, 3, and 5-9) performing histopathology testing (TP #2 and 3 performing interpretations of histopathologic slides and TP #5-9 performing grossing of the histopathologic specimens) from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026. 2. Review of laboratory policies and procedures revealed a lack of documentation of a competency assessment procedure in place for all aspects of histopathology testing (interpretation and grossing). 3. Interview with TP #5 on 04/20/2026, at 9:49 am, confirmed the laboratory failed to establish and follow written policies and procedures to assess seven of seven TP competencies in the subspecialty of histopathology.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: A) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to document the check of positive and negative reactivity / quality control (QC) of immunohistochemical (IHC) stains each time of use for three of three histopathology patients reviewed that utilized IHC staining material. Findings include: 1. Review of laboratory policies and procedure revealed the procedure titled "Quality Assurance Plan", which stated, under "4. Quality Control", "a. Run appropriate control samples with each batch of testing. b. Record control results and verify they fall within established acceptable ranges. c. Investigate and document any out-of-range control results." 2. Upon review of patient test records and corresponding QC logs, it was revealed that three of three histopathology patients reviewed that utilized IHC stain failed to have checks of positive and negative reactivity / QC documented prior to reporting patient results. Accession #: Report Date: IHC Stain: VS26-0693 01/21 /2026 MelanA, Sox10, & Prame VS26-2610 02/26/2026 MelanA, Sox10, & Prame VS26-4601 04/02/2026 EpCAM* *EpCAM = Epithelial Cell Adhesion Molecule 3. Interview with TP #5 on 04/20/2026, at 1:04 pm, confirmed the laboratory failed to document the check of positive and negative reactivity / QC of IHC stains each time of use for three of three histopathology patients reviewed that utilized IHC staining material. _____ B) Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to document a control slide of known reactivity of special stains with each patient slide or group of patient slides for three of three histopathology patients reviewed that utilized special staining material. Findings include: 1. Review of laboratory policies and procedure revealed the procedure titled "Quality Assurance Plan", which stated, under "4. Quality Control",

	"a. Run appropriate control samples with each batch of testing. b. Record control results and verify they fall within established acceptable ranges. c. Investigate and document any out-of-range control results." 2. Upon review of patient test records and corresponding control logs, it was revealed that three of three histopathology patients reviewed that utilized special staining material failed to have a control slide of known reactivity documented prior to reporting patient results. Accession #: Report Date: Special Stain: VS26-2610 02/26/2026 PAS* VS26-4585 04/02/2026 PAS, GRAM** VS26-4601 04/02/2026 PAS *PAS = Periodic acid-Schiff **GRAM = Gram Stain 3. Interview with TP #5 on 04/20/2026, at 1:04 pm, confirmed the laboratory failed to document a control slide of known reactivity of special stains with each patient slide or group of patient slides for three of three histopathology patients reviewed that utilized special staining material.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to perform corrective actions for out of range temperature and humidity readings that did not meet the laboratory's established performance specifications for four of four testing dates reviewed affecting patient testing in the subspecialty of histopathology from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Assurance Plan", which stated, under "6. Non-Conformance and Corrective Actions", "a. Document any errors, deviations, or non-conformances. b. Investigate root causes and implement corrective actions. c. Record corrective actions taken and monitor their effectiveness." 2. Review of laboratory temperature and humidity logs revealed the following temperature and humidity readings that did not meet the laboratory's established performance specifications: i. Date: 01/16/2026 Equipment / Room: Acceptability Range: Measured: Oven Temp #1 56 - 61C 62C Oven Temp #2 56 - 61C 62C Slide Oven Temp 63 - 65C 65.6C Freezer Temp -23 - -17C -16.8C Chemical Storage RT* 68 - 77C 65C Room #2 Humidity 20 - 40% 18% *RT = Room Temp ii. Date: 02/23/2026 Equipment / Room: Acceptability Range: Measured: Oven Temp #1 56 - 61C 62C Paraffin Temp #1 56 - 61C 68C Oven Temp #2 56 - 61C 62C Slide Oven Temp 63 - 65C 65.4C Fridge #2 Temp 2 - 8C 1C Stock Room Temp 68 - 77C 64C Chemical Storage RT 68 - 77C 60C Room #1 Humidity 20 - 40% 16% Room #2 Humidity 20 - 40% 13% iii. Date: 03/27/2026 Equipment / Room: Acceptability Range: Measured: Oven Temp #1 56 - 61C 62C Oven Temp #2 56 - 61C 62C Slide Oven Temp 63 - 65C 65.3C Water Bath Station #1 40 - 45C 37.5C Water Bath Station #2 40 - 45C 37.3C Water Bath Station #3 40 - 45C 38.1C Freezer Temp -23 - -17C -15.5C Chemical

	Storage RT 68 - 77C 67C iv. Date: 03/30/2026 Equipment / Room: Acceptability Range: Measured: Oven Temp #1 56 - 61C 62C Oven Temp #2 56 - 61C 63C Water Bath Station #1 40 - 45C 37.5C Water Bath Station #2 40 - 45C 37.2C Water Bath Station #3 40 - 45C 37.6C Freezer Temp -23 - -17C -14.9C Chemical Storage RT 68 - 77C 67.8C 3. Interview with TP #5 on 04/20/2026, at 1:49 pm, confirmed the laboratory failed to perform corrective actions for out of range temperature and humidity readings that did not meet the laboratory's established performance specifications for four of four testing dates reviewed affecting patient testing in the subspecialty of histopathology from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory director (LD) failed to ensure documentation of the check of positive and negative reactivity of immunohistochemical (IHC) stains each time of use for three of three histopathology patients reviewed that utilized IHC staining material and failed to ensure documentation of a control slide of known reactivity of special stains with each patient slide or group of patient slides for three of three histopathology patients reviewed that utilized special staining material (see D6093), failed to ensure the performance of corrective actions for out of range temperature and humidity readings that did not meet the laboratory's established performance specifications for four of four testing dates reviewed (see D6096), and failed to ensure that prior to testing patients' specimens, one of five TP performing high complexity specimen grossing had the appropriate education and experience, seven of seven TP performing testing in the subspecialty of histopathology received 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 (see D6102).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory director failed to ensure documentation of the check of positive and negative reactivity of immunohistochemical (IHC) stains each time of use for three of three histopathology patients reviewed that utilized IHC staining material (see D5601a) and failed to ensure documentation of a control slide of known reactivity of special stains with each

	patient slide or group of patient slides for three of three histopathology patients reviewed that utilized special staining material (see D5601b).
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory director failed to ensure the performance of corrective actions for out of range temperature and humidity readings that did not meet the laboratory's established performance specifications for four of four testing dates reviewed affecting patient testing in the subspecialty of histopathology from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026 (see D5781).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory director (LD) failed to ensure that prior to testing patients' specimens, one of five TP performing high complexity specimen grossing had the appropriate education and experience, seven of seven TP performing testing in the subspecialty of histopathology received 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, affecting 10,435 patients. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form, signed by the laboratory director on 04/15/2026, revealed seven TP (TP #2, 3, and 5-9) performing histopathology testing (TP #2 and 3 performing interpretations of histopathologic slides and TP #5-9 performing grossing of the histopathologic specimens) from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026. 2. Review of laboratory personnel and educational records revealed a lack of qualifying documentation for one of five TP (TP #9) performing high complexity grossing of the histopathologic specimens (see D6168). 3. Review of laboratory policies and procedures revealed the procedure titled "Quality Assurance Plan", which stated, under "7. Staff Training and Competency", "a. Ensure all personnel are trained ...." 4. Review of laboratory personnel and educational records revealed a lack of documentation of training records for seven of seven TP performing histopathology testing. 5. Interview with TP #5 on 04/20/2026, at 10:14 am, confirmed the LD failed to ensure that prior to testing patients' specimens, one of five TP performing high complexity specimen grossing

	had the appropriate education and experience, seven of seven TP performing testing in the subspecialty of histopathology received 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, affecting 10,435 patients.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory personnel and education records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to ensure one of five TP performing specimen grossing was qualified for high complexity testing in the subspecialty of histopathology (see D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in

	respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory personnel and education records, lack of documentation, and interview with testing personnel (TP) #5; the laboratory failed to ensure one of five TP performing specimen grossing was qualified for high complexity testing in the subspecialty of histopathology. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form, signed by the laboratory director on 04/15/2026, revealed five TP (TP #5-9) performing grossing of the histopathologic specimens from the effective date of the Certificate of Registration, 12/01/2025, through the date of survey, 04/20/2026. 2. Review of laboratory personnel and educational records revealed a lack of educational and training documentation for one of five TP (TP #9) performing high complexity grossing of the histopathologic specimens. 3. Interview with TP #5 on 04/20/2026, at 9:39 am, confirmed the laboratory failed to ensure one of five TP performing specimen grossing was qualified for high complexity testing in the subspecialty of histopathology.