DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202	2/10/2025-2/20/2025* FEI NUMBER 1034569

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dominique G. Petitgenet, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Immucor, Inc.	3130 Gateway Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Norcross, GA 30071	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically,

On 2/18/2025, we observed approximately 6 HEPA filters with apparent biological growth in building (b) (4) production rooms (b) (4) and (b) (4) utilized in the bulk manufacturing of reagent red blood cells. Your preventative maintenance of these HEPA filters in building (b) (4), production rooms (b) (4) and (b) (4) failed to include a visual inspection.

The installation dates of the HEPA filters located in building (b) (4), production rooms (b) (4) and (b) (4) were:

- HEPA filter (b) (4) room (b) (4) was installed 04/01/2009.
- HEPA filter (b) (4) room (b) (4) was installed 04/01/2009.
- HEPA filter (b) (4) room (b) (4) was installed 04/01/2009.
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- HEPA filter (b) (4) room (b) (4) was installed 04/01/2009.
- HEPA filter (b) (4) room (b) (4) was installed 09/10/2009.

Your firm has failed to ensure these HEPA filters are maintained, adjusted, cleaned, and used in a manner that prevents contamination of bulk manufacturing of reagent red blood cells in building (b) (4), production rooms (b) (4) and (b) (4).

AMENDMENT 1

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EMPLOYEE(S) SIGNATURE
Cody D Rickman, Investigator
Edward A Brunt, Investigator
Kimberly M Bigler, FDA Center Employee
Emilia A Sippert, FDA Center Employee

X Cody D Rickman Investigator Signed By: Cody D. Rickman -S Date Signed: 03-10-2025 14:44:18

DATE ISSUED
3/10/2025

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Since 07/30/2021, your firm has received the following complaints for reagent red blood cells manufactured in building (b) (4) production rooms (b) (4) and (b) (4)

- Unexpected negative test results – 474
- Unexpected positive test results – 2,166
- Hemolyzed – 291
- Unexpected color – 235
- Clots – 64
- Particulate – 73

Your firm's safety hazard assessments for reagent red blood cells detail the root causes for the following hazards for unexpected negative test results, positive test results, hemolyzed, unexpected color, clots, and particulate as bacterial or chemical contamination.

Your firm's safety hazard assessments identify the following patient hazards from product with bacterial or chemical contamination:

- Results in permanent impairment or life-threatening injury.
- Life-threatening condition is where Major intervention is required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.
- Delay in providing test results would lead to delay in blood transfusion resulting in: Temporary injury or impairment not requiring professional medical intervention.

OBSERVATION 2

Procedures for corrective and preventive action have not been adequately established.

Specifically,

Your firm failed to follow standard operating procedure 00.SOP.0002, titled Corrective and Preventative

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Action, effective 06/22/2022, regarding the investigation and corrective and preventative actions taken with CAPA 1034646 (opened 07/03/2024) generated in response to adverse complaint trends associated with Panoscreen® III lot 17845, Panoscreen® I, II lot 18915, Panocell® 10 lot 17905, Panocell® 10 Ficin lot 19919-E, and Panocell® 10 lot (b) (4) (licensed reagent red blood cells) for unexpected color (attributed to microbiological contamination):

-Investigating the cause of nonconformities related to product, processes, and the quality system.
  - oFailure to visually assess and investigate air handling units providing air to building (b) (4), production rooms (b) (4) and (b) (4).
  - oFailure to visually assess and investigate approximately 11 HEPA filters located in building (b) (4), production rooms (b) (4) and (b) (4).
  - oFailure to identify the route of introduction of the microbiological contamination into the finished product.

-Identifying actions to correct and prevent recurrence of nonconforming product and other quality problems were not addressed in the investigation and CAPA documents (Scope other lots impacted).
  - oFailure to perform a risk assessment to identify the impact on other products and lots manufactured in building (b) (4) production rooms (b) (4) and (b) (4)

Your firm's standard operating procedure 00.SOP.0002, titled Corrective and Preventative Action, effective 06/22/2022, fails to address initiating a CAPA investigation regarding trending significant consumer complaints. Since 07/30/2021, the following consumer complaints were not initiated as a CAPA investigation:

-Anti-D (Monoclonal Blend) series 4 and 5, in various packaging configurations (licensed blood grouping reagents) – 480 complaints (unexpected reaction positive, negative, or weak reactivity).
- (b) (4), in various packaging configurations (b) (4) – 1,684 complaints (unexpected reaction positive, negative, or weak reactivity).
-Referencells® A1B 2x10ml (licensed reagent red blood cells) lot (b) (4) – 18 complaints (14 unexpected color and 4 hemolyzed).

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OBSERVATION 3
Products that do not conform to specifications are not adequately controlled.

Specifically,

Standard operating procedures have not been adequately established to control products (vialed reagents such as blood grouping reagents, reagent red blood cells, anti-human globulin, (b) (4) (b) (4), etc.) in determining a need for investigation when reject thresholds have been surpassed or deviate from normal production rejection rates.

Your firm tracks and documents reject rates for vialed reagent products made by the (b) (4) visual inspection system and a (b) (4) 100% visual inspection. Reject reasons are categorized for the (b) (4) 100% visual inspection but your firm failed to establish a threshold limit for reject types. Your firm failed to establish trending analysis for reject reasons discovered during (b) (4) 100% visual inspection.

OBSERVATION 4
Risk analysis is inadequate and is incomplete.

Specifically,

1) The risk analysis and the risk assessments conducted for Panoscreen® I, II, III 3x10 mL (licensed reagent red blood cells) products fail to include risks associated with using the products on other testing instrument technology.

- According to complaints received, intended users utilized Panoscreen® I, II, III 3x10 mL (licensed reagent red blood cells) products on gel technology.
- The instructions for use fails to instruct intended users for Panoscreen® I, II, III 3x10 mL (licensed reagent red blood cells) is not validated for gel technology.

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2) The risk analysis and risk assessments conducted for Anti-D (Monoclonal Blend) series 4 and 5, in various packaging configurations (licensed blood grouping reagents) products fail to include risks associated with unexpected reaction positive, negative, or weak reactivity and No Type Determined (NTD) results for the ABO Rh testing when these reagents are used to perform D typing onboard the Neo Iris and Echo Lumena automated platforms.

- According to 480 complaints received, intended users utilize Anti-D (Monoclonal Blend) series 4 and 5, in various packaging configurations (licensed blood grouping reagents) products per instructions in IFUs and continue to generate weak reactive or unexpected results.
- The instructions for use for the Anti-D (Monoclonal Blend) Series 4 and 5, refer intended users to the operator's manual for the Neo Iris and Echo Lumena automated platforms. The operator's manual for the Neo Iris and Echo Lumena automated platforms fail to include information regarding the use of Anti-D (Monoclonal Blend) Series 4 and 5 reagents may result in unexplained reactivity due to RhD variants.

3) The risk analysis and risk assessments conducted for both the (b) (4) (b) (4) in various packaging configurations (b) (4) platelet antibody test) products fail to include the risk associated with the use of platelets from one random uncharacterized platelet antigen donor which may lead to unexpected negative results. A false negative test result could lead to the transfusion of antigen positive platelets to a patient with the corresponding IgG antibody resulting in platelet refractoriness leading to potential bleeding requiring professional medical attention.

OBSERVATION 5

Procedures have not been adequately established to control product that does not conform to specified requirements.

Specifically,

According to standard operating procedure 01.SOP.0089, titled Conducting Root Cause Investigations,

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section 1.14 an interim report (or progress statement, at a minimum) is required every (b) (4) business days for investigations that will not close within (b) (4) business days from initiation and every (b) (4) business days until closure. Quality Unit consultation is required for exceptions. Rationale must be documented in the appropriate summary field and/or attachment.

Approximately 7 Reporting Complaint Investigation Reports failed to have rationale for not completing an interim report within (b) (4) business days as required in 01.SOP.0089, titled Conducting Root Cause Investigations, section 1.14.

OBSERVATION 6
Written MDR procedures have not been developed.

Specifically,

Standard operating procedure 01.SOP.0108 titled Medical Device Events, section 1.1.2 fails to include unexpected false positive results for the (b) (4) (b) (4) Panoscreen®, Panocell®, and (b) (4) as potential MDRs. Unexpected positive reactions mask clinically significant alloantibodies complicating antibody identification procedures.

The following complaints attributed to unexpected positive reactions were not assessed for MDR reportability:

- Approximately 25 Panoscreen®
- Approximately 49 Panocell®
- Approximately 1,042 (b) (4)
- Approximately 804 (b) (4)
- Approximately 235 (b) (4)

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OBSERVATION 7

A justification for not reporting the correction or removal action to FDA that included conclusions, follow-ups and reviews by a designated person was not included in the record.

Specifically,

According to standard operating procedure 01.SOP.0107, titled Product Field Action, section 2.2.2 if the correction or removal qualifies as an exemption (non-reportable correction/removal), then justification must be documented on 01.(b) (4).0198 Field Action (b) (4), the following elements must be included in the 01.(b) (4).0198 Field Action Checklist, name and intended use of the device, UDI for the device, a description of the event, justification for not reporting (including any conclusions and follow-ups), and copy of any communication regarding the correction or removal.

The 01.(b) (4).0198 Field Action Checklists fail to include a description of the event and a justification for not reporting the following correction and removals reports:

-FA-(b) (4)-23-02 (b) (4)
-FA- -23-05 (ImmuLINK)
-FA- -24-01 (Panocell-10)
-FA- -24-07 (ImmuLINK)

*DATES OF INSPECTION

2/10/2025(Mon), 2/11/2025(Tue), 2/12/2025(Wed), 2/13/2025(Thu), 2/14/2025(Fri), 2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

Observation 7: Corrected and verified

AMENDMENT 1

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."