

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404		DATE(S) OF INSPECTION 2/25/2025-2/26/2025 FEI NUMBER 3028586894	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Stacy H. Shomento, M.D., Medical Director			
FIRM NAME Billings Clinic Fertility Specialists		STREET ADDRESS 925 Highland Blvd Ste 1210	
CITY, STATE, ZIP CODE, COUNTRY Bozeman, MT 59715-6905		TYPE ESTABLISHMENT INSPECTED Reproductive Tissue	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 HCT/P donors were not determined to be eligible based on the results of donor screening and testing.</p> <p>Specifically,</p> <p>During review of donor eligibility records, the following ineligible donors were determined by you to be eligible.</p> <ol style="list-style-type: none"> Directed oocyte donor (b) (6), (b) (7)(C) did not complete a "Donor Risk Behavior Assessment." The donor was deemed eligible on (b) (6), (b) (7)(C)/2023. This donor previously completed the questionnaire (b) (6), (b) (7)(C)/2021. The donor's tissue was recovered on (b) (6), (b) (7)(C)/2023 and utilized in a transfer on (b) (6), (b) (7)(C)/2023. Directed semen donor (b) (6), (b) (7)(C) did not complete a "Donor Risk Behavior Assessment." The donor was deemed eligible on (b) (6), (b) (7)(C)/2023. This donor previously completed the questionnaire (b) (6), (b) (7)(C)/2021. The donor's tissue was recovered on (b) (6), (b) (7)(C)/2023 and utilized in a transfer on (b) (6), (b) (7)(C)/2023. Directed semen donor (b) (6), (b) (7)(C) answered "Yes" to the following questions: "Are you a male who has had sex with another male in the preceding five years?" "Since 1977, have you or any of your intimate contacts ever traveled to or lived in Europe or Africa?" Per your standard operating procedure (SOP) <i>Reproductive Donor Eligibility Determination</i>, the donor should be deemed ineligible based on these answers and further investigation and documentation should be completed. (b) (6), (b) (7)(C) was deemed eligible by your firm on (b) (6), (b) (7)(C)/2021. Tissue was collected on (b) (6), (b) (7)(C)/2021. 			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Emily S McGann, Investigator <div style="text-align: right; font-size: small;"> Emily S McGann Investigator Signed By: Emily S. McGann -G Date Signed: 02-26-2025 16:00:43 X _____ </div>	
		DATE ISSUED 2/26/2025	

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<small>CITY, STATE, ZIP CODE, COUNTRY</small> Bozeman, MT 59715-6905		<small>TYPE ESTABLISHMENT INSPECTED</small> Reproductive Tissue	
<p>4. Directed semen donor (b) (6), (b) (7)(C) answered "Yes" to the following question: "Since 1977, have you or any of your intimate contacts ever traveled to or lived in Europe or Africa?" er your standard operating procedure (SOP) <i>Reproductive Donor Eligibility Determination</i>, the donor should be deemed ineligible based on these answers and further investigation and documentation should be completed. (b) (6), (b) (7)(C) was deemed eligible by your firm on (b) (6), (b) (7)(C)/2021. Tissue was collected on (b) (6), (b) (7)(C)/2021 and was transferred on (b) (6), (b) (7)(C)/2021.</p> <p>This issue was found in four (4) of fourteen (14) cases reviewed.</p> <hr/> <p>OBSERVATION 2 Donors were not tested for evidence of infection with relevant communicable disease agents.</p> <p>Specifically,</p> <p>During review of donor records, directed semen donor (b) (6), (b) (7)(C) was deemed eligible on (b) (6), (b) (7)(C)/2023 by your firm, but no gonorrhea or chlamydia testing was completed. The reproductive tissue was collected on (b) (6), (b) (7)(C)/2023 and was used in a transfer on (b) (6), (b) (7)(C)/2023.</p> <p>This issue was found in one (1) of fourteen (14) cases reviewed.</p> <hr/> <p>OBSERVATION 3 The eligibility of an HCT/P donor was not by a responsible person, based on results of donor screening and donor testing.</p> <p>Specifically,</p> <p>Directed semen donor (b) (6), (b) (7)(C) had no eligibility determination made. The tissue collection occurred on (b) (6), (b) (7)(C)/2021. A transfer of tissue was completed on (b) (6), (b) (7)(C)/2022.</p>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Emily S McGann, Investigator <div style="text-align: right;"> <small>Emily S McGann Investigator Signed By: Emily S. McGann -G Date Signed: 02-26-2025 16:00:43</small> X _____ </div>	
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TYPE ESTABLISHMENT INSPECTED

Reproductive Tissue

This issue was found in one (1) of fourteen (14) cases reviewed.

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Emily S McGann, Investigator

Emily S McGann
Investigator
Signed By: Emily S. McGann -S
Date Signed: 02-26-2025
16:00:43

X

DATE ISSUED

2/26/2025

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."