

| <b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b><br><b>FOOD AND DRUG ADMINISTRATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                          |                                                                                                                                                                                              |                                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| <small>DISTRICT ADDRESS AND PHONE NUMBER</small><br>550 Main Street, Ste 4-930<br>Cincinnati, OH 45202<br>(513) 322-0700 Fax: (513) 679-2772                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                          | <small>DATE(S) OF INSPECTION</small><br>5/6/2025-5/15/2025*<br><small>FEI NUMBER</small><br>3015173692                                                                                       |                                         |
| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Wendy G. Smith, IVF Lab Supervisor                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                          |                                                                                                                                                                                              |                                         |
| <small>FIRM NAME</small><br>Ohio Fertility Providers LLC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                          | <small>STREET ADDRESS</small><br>3805 Edwards Rd Ste 455                                                                                                                                     |                                         |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Cincinnati, OH 45209-1948                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                          | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Human 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><b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b><br/> <b>OBSERVATION 1</b><br/>           HCT/Ps were not kept in quarantine until completion of the donor-eligibility determination.</p> <p>Specifically,</p> <p>Donor [REDACTED] was found during the previous inspection on [REDACTED] to have an incomplete donor history questionnaire from donation on 07/05/2023. [REDACTED] oocytes were cryopreserved from this donation. These oocytes were not kept in quarantine and were [REDACTED] Tissue created from these oocytes was transferred to a recipient on [REDACTED]. An exemption request was not obtained.</p> |                                                                          |                                                                                                                                                                                              |                                         |
| <p><b>OBSERVATION 2</b><br/>           HCT/Ps for which the applicable donor eligibility requirements were not met were not prominently labeled with the appropriate warning statements.</p> <p>Specifically,</p> <p>Donor tissue screened with an incomplete donor history questionnaire from the last inspection ending on 08/30/2023 were not labeled with the required warning statements. "Not evaluated for infectious</p>                                                                                                                                                                                                   |                                                                          |                                                                                                                                                                                              |                                         |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <small>EMPLOYEE(S) SIGNATURE</small><br>Jennifer L Sheehan, Investigator |                                                                                                                                                                                              | <small>DATE ISSUED</small><br>5/15/2025 |
| <small>Signature of Investigator</small><br>_____<br>X                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                          | <small>Investigator</small><br>Jennifer L. Sheehan<br><small>Signed By:</small> Jennifer L. Sheehan<br><small>S</small><br><small>Date Signed:</small> 05-15-2025<br><small>07:43:36</small> |                                         |

| <b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b><br><b>FOOD AND DRUG ADMINISTRATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
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| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Wendy G. Smith, IVF Lab Supervisor                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <small>FIRM NAME</small><br>Ohio Fertility Providers LLC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | <small>STREET ADDRESS</small><br>3805 Edwards Rd Ste 455                                                                                                                                                                                                                                                                                                                                                                                          |  |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Cincinnati, OH 45209-1948                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Human Reproductive Tissue                                                                                                                                                                                                                                                                                                                                                                          |  |
| <p>substances" and "WARNING: advise recipient of communicable disease risk".</p> <p>Examples:</p> <p>Donor <span style="border: 1px solid black; padding: 0 20px;"> </span> was found during the previous inspection to have an incomplete donor history questionnaire. There were no warning statements present for this HCT/P.</p> <p>Donor <span style="border: 1px solid black; padding: 0 20px;"> </span> was found during the previous inspection to have an incomplete donor history questionnaire. There were no warning statements present for this HCT/P.</p> |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <p><b>*DATES OF INSPECTION</b></p> <p>5/06/2025(Tue), 5/07/2025(Wed), 5/12/2025(Mon), 5/15/2025(Thu)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Jennifer L Sheehan, Investigator<br><br><div style="text-align: right;"> <small>Jennifer L Sheehan<br/>Investigator<br/>Signed By: Jennifer L. Sheehan<br/>S<br/>Date Signed: 05-15-2025<br/>07:43:36</small><br/> <div style="border-top: 1px solid black; width: 100px; margin-top: 5px;"> <span style="position: absolute; left: -10px; top: 50%; transform: translateY(-50%);">X</span> </div> </div> |  |
| <small>DATE ISSUED</small><br>5/15/2025                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |

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."