INVESTIGATIONAL USE ONLY PRODUCT EVALUATION PROGRAM

This Investigational Use Only Product Agreement (the "Agreement") governs the use of the *BioFire® Bone and Joint Infection (BJI) Panel* (the "BioFire BJI Panel" or the "Panel"). By accepting delivery of the BioFire BJI Panel, _____ ("Institution") agrees to the following terms and conditions of **BioFire Diagnostics, LLC**, a bioMérieux company, and a Delaware limited liability company with a primary place of business at 515 Colorow Drive, Salt Lake City, UT 84108 ("BFDX").

1. BFDX shall provide Institution two (2) kits of the BioFire BJI Panel free of charge when it is available. The Panel is for *Investigational Use Only*, which means it will only be used in clinical studies that meet the definition of an "Exempted Investigation" under 21 C.F.R. 812.2(c)(3). Institution agrees that the Panel will not be used as part of any diagnostic procedure without confirmation by another, medically-established diagnostic product or procedure.
2. The Panel has not been cleared by the FDA, is still in development by BFDX, and has not been released for general sale. All rights in and to the Panel is owned solely by BFDX. Institution will not provide third parties access to the Panel unless BFDX provides prior written permission for such access. Participation in the Evaluation Program and use of the Panel will require that an IUO software module be installed on the BioFire® FilmArray® System which the Institution will use to run the Panel. If the Panel is cleared by the FDA as an IVD product, the software will be updated to conform to the cleared product.
3. In return for being part of the Evaluation Program, Institution will inform BFDX of any problems with the Panel and shall provide general feedback to BFDX regarding the performance of the Panel.
4. BFDX further requests Institution provide feedback to BFDX regarding the scientific and other characteristics of the Panel compared to the standard of care by completing a survey (the "Survey"). In the event Institution elects to participate in the Survey, the Parties agree as follows:
    a. When responding to the Survey, Institution will remove all patient and/or personal data and will not provide any health information protected under applicable laws and regulations (including any sensitive medical information that is not allowed to disclosed to any third party), to BFDX.
    b. Institution represents that it has obtained all required authorizations, within their Institution guidelines or otherwise, to disclose the responses shared in the Survey and to permit BFDX to use the information contained in the Survey for the purposes described in Section 4(d) and 4(e).
    c. Institution will comply with applicable data protection laws with respect to their processing (if any) of the personal information they collect, transfer, or receive related to this Agreement.
    d. All data obtained through the Survey shall be aggregated and shall not be identified by region or Institution. BFDX may use the Survey results for internal research and development purposes, as well as for any commercial or promotional purpose, including in connection with any products, promotion, financing, advertising, or sales literature.
    e. BFDX may publish results obtained under the Survey. In the event BFDX does publish such results, the Institution will be recognized as an author under an authorship consortium and, by participating in the Survey, you authorize BFDX to use your name in conjunction with such a publication. In the event a publication does occur, data shall be aggregated as described in Section 4(d). Each participating Institution shall have the right to review and comment on the publication before it is finalized.

5. Institution may publish results obtained using the Panels, provided that Institution submits any such proposed publication to BFDX at least ninety (90) days prior to submission so that BFDX may review the proposed publication to remove any confidential or proprietary information of BFDX, or correct any factual errors regarding the Panel. Proposed publications will be sent to Medical.Affairs@biofiredx.com.
6. The Panels are not covered by any warranty, and problems may be encountered when the Panel are used. BFDX WILL HAVE NO LIABILITY TO INSTITUTION FOR ANY KIND OF DAMAGES ARISING OUT OF USE OF THE PANEL WHICH IS NOT IN STRICT COMPLIANCE WITH THE TERMS SET FORTH IN THIS AGREEMENT AND THE IFUs FOR THE PANEL. INSTITUTION AGREES TO INDEMNIFY AND HOLD BFDX HARMLESS FROM ANY CLAIM RELATED TO A USE BY INSTITUTION THAT IS NOT PERMITTED BY THIS AGREEMENT.
7. Institution acknowledges that BFDX is required by federal law to publicly disclose any transfers of value made to Institution.
8. Institution further agrees that this Evaluation Program is not intended as a reward or inducement for the purchase, ordering, or referral of BFDX's products as prohibited by the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) and any similar applicable state law(s) or law(s) of foreign jurisdictions.
9. Institution may not assign its rights or obligations under this Agreement.
10. The Panels are governed by United States export control laws and regulations, including but not limited to restrictions on use, re-exports, and deemed exports of the Panels.
11. Either party may terminate this Agreement upon notice to the other.
12. Paragraphs 1, 2, 4-7, 9-12 will survive either the termination or expiration of this Agreement.
13. This Agreement constitutes the entire agreement and understanding between the parties and supersedes any and all prior agreements or understandings with respect to the subject matter. This Agreement may only be modified by an agreement in writing executed by the parties. The undersigned represents to BFDX that she has authority to execute this Agreement on behalf of the Institution.

Accepted and agreed to this ____ day of _____ 2020 by:

[Institution-Legal Name]

By _____

Name (print) _____

Title _____

If a 2020 CMS Teaching Hospital

Registered Name: _____

TIN: _____

Registered Address: _____