May 15, 2018

David F. Stroncek, MD
William Ward, PhD, D(ABHI)
HLA Laboratory
National Institutes of Health
Bldg. 10, Rm 1C744
10 Center Drive
Bethesda MD 20892-1184

RE: ASHI Accreditation No. 05-2-MD-09-1
CLIA No. 21D0662289
UNOS No.

Dear Dr. Stroncek and Dr. Ward:

I have received and reviewed all of the validation materials sent to me by Christina Bishop, PhD, D(ABHI), your ASHI Commissioner, in regards to the addition of Next Generation Sequencing (NGS) testing. I am in concurrence with the recommendations of your Commissioner that your laboratory has successfully demonstrated compliance with all mandatory ASHI Standards.

On the basis of the recommendations from your Commissioner, the HLA Laboratory of the National Institutes of Health, 05-2-MD-09-1, under the direction of David F. Stroncek, MD and William Ward, PhD, D(ABHI) is granted accreditation for the following:

**Areas of Accreditation:**
- Histocompatibility Testing For Other Clinical Purposes
- Transfusion Support

**Categories & Systems:**

<table>
<thead>
<tr>
<th>HLA Typing Class I: Low Resolution</th>
<th>HLA Antibody Detection: Solid phase</th>
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<tbody>
<tr>
<td>HLA Typing Class I: High Resolution</td>
<td>HLA Antibody Identification: Solid phase</td>
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<tr>
<td>HLA Typing Class II: Low Resolution</td>
<td>Next Generation Sequencing</td>
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<tr>
<td>HLA Typing Class II: High Resolution</td>
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<td>KIR Genotyping</td>
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Accreditation for the above areas of accreditation, categories, and systems will be valid until 4/30/2020, pending successful completion of an interim, self-inspection cycle next year. Your laboratory is accredited by ASHI for the following CMS subspecialties: Histocompatibility Testing.

You and your laboratory staff are to be commended for maintaining ASHI’s high standards for laboratory performance and patient service.

Should you have any questions about the inspection or accreditation process, please contact the appropriate commissioner or the ASHI Accreditation Office at (651) 202-3637.

Sincerely,

Nancy Higgins, BS, CHS
Co-Chair, ASHI Accreditation Review Board

cc: Christina Bishop, PhD, D(ABHI), Commissioner
    Zahra Mehdi-zadeh Kashi, PhD, HCLD, Program Director
    David Kiger, CHS, Co-Chair
    John Gerlach, PhD, D(ABHI), Co-Chair
    Melissa Weeks, Accreditation Manager