**STATEMENT**

**REQUIREMENTS FOR THE TENDERER**

**RFP 026653 - DEVELOPMENT AND VALIDATION OF NEUTRALIZING ANTIBODY ASSAYS FOR THE ASSESSMENT OF ANTI-DRUG ANTIBODY ACTIVITY AGAINST A BIOLOGIC THERAPY**

|  |  |
| --- | --- |
| **REQUIREMENTS** | **CONFIRMATION [YES/NO]** |
| A minimum of three (3) years of documented experience in the development and validation of both cell-based and non-cell-based assays for the determination of neutralizing antibody (NAb) activity in the context of oncological therapies |  |
| Demonstrated capability to handle and process human serum samples originating from clinical studies |  |
| Demonstrated capability to handle complex biologics (e.g. multifunctional and multidomain molecules) and mechanism-specific neutralization assays |  |

**………………………………**

*(date and signature of Tenderer's authorized representative)*