|  |  |
| --- | --- |
| **Purpose** | □ Prospective Validation/Qualification□ Retrospective□ Revalidation |
| **System Description** |

|  |  |
| --- | --- |
| Manufacturer |  |
| Model |  |
| Serial Number(s) |  |

 |
| **Technical Specifications** |

|  |  |
| --- | --- |
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|  |  |

 |
| **Critical Control Points** |  |
| **Name of SOPs involved** |  |
| **Responsibilities** |  |
| **Reagents, Supplies and Equipment Required** |  |
| **Installation Qualification** |  |
| **Operational Qualification** |  |
| **Performance Qualification** |  |

 **VALIDATION PLAN APPROVAL**

Signature/Transfusion Service Manager Date

Signature/Transfusion Service Compliance Analyst Date

Signature/Transfusion Service Medical Director Date

Installation Qualification (Insert)

Operational Qualification (Insert)

Performance Qualification (Insert)

Validation Summary -

|  |  |
| --- | --- |
| Manufacturer |  |
| Model |  |
| Serial Number(s) |  |

* Installation Qualification
* Operational Qualification
* Performance Qualification

Validation is Acceptable: Yes / No

Document Action Plan if Validation is not acceptable

Go Live Implementation Date:

Signature/Transfusion Service Manager Date

Signature/Transfusion Service Compliance Analyst Date

Signature/Transfusion Service Medical Director Date