**Planned Deviation Documentation**

|  |  |
| --- | --- |
| Site(s): | SGMC |
| Procedure: | Atellica – Vitamin B12 |
| Reason for Deviation: | Supply Chain Critical Shortage for Vitamin B12 diluent. Values which exceed the upper AMR (>2,000 pg/mL) are diluted with onboard VB12 diluent to extend the CRR to 20,000 pg/mL. Vitamin B12 diluent is currently on backorder. Once VB12 diluent supply is exhausted, values which exceed the AMR (>2,000 pg/mL) will be reported as “>2,000 pg/mL”.  |
| Medical Director or Designee: | Dr. Cacciabeve | Date: 9/8/2022 |
| Supervisor: | H. Genser | Date: 9/8/2022 |
| Deviation Start Date: | 9/9/2022 | Deviation End Date: TBD |
|  |  |  |  |  |
| Testing Personnel Signatures | Start Deviation Signatures |  | End Deviation Signatures |  |
| Printed Name / Tech Code | Signature | Date | Signature | Date |
| MTS |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |