

## Certificate of Analysis

Product Name: Coag Control Level 1 (Normal) - Orig:USA  
Product Number: 100595  
Lot Number: 234088

Expiration Date: 05/31/2020  
Storage: 2 - 8°C

| Specification            | Specification Limit                                                                                    | Result        |
|--------------------------|--------------------------------------------------------------------------------------------------------|---------------|
| Appearance               | Yellow to buff colored solid                                                                           | Complies      |
| Appearance Reconstituted | Yellow to straw colored, clear to hazy,<br>free of particulates when viewed against<br>dark background | Complies      |
| Solubility               | Less than 2 minutes                                                                                    | Complies      |
| Vial-to-vial Variability | <= 1.8 %                                                                                               | 0.8           |
| Moisture                 | <= 3 %                                                                                                 | 1             |
| Thromboplastin DS        | Report                                                                                                 | 14.8 S        |
| Thromboplastin DS        | Confidence Interval*                                                                                   | 12.6-17.0 S   |
| Thromboplastin DS        | Value % PT                                                                                             | 76 %          |
| Thromboplastin DS        | Confidence Interval*                                                                                   | 61-91 %       |
| Thromboplastin D         | Lower Limit                                                                                            | 12.0 S        |
| Thromboplastin D         | Upper Limit                                                                                            | 13.7 S        |
| Thromboplastin D         | Result                                                                                                 | 13.2 S        |
| Thromboplastin D         | Confidence Interval*                                                                                   | 11.2-15.2 S   |
| Thromboplastin D         | Value % PT                                                                                             | 74 %          |
| Thromboplastin D         | Confidence Interval*                                                                                   | 59-89 %       |
| APTT-XL                  | Lower Limit                                                                                            | 28 S          |
| APTT-XL                  | Upper Limit                                                                                            | 35 S          |
| APTT-XL                  | Result                                                                                                 | 35 S          |
| APTT-XL                  | Confidence Interval*                                                                                   | 29.3-39.7 S   |
| Kontakt                  | Report                                                                                                 | 32 S          |
| Kontakt                  | Confidence Interval*                                                                                   | 27.2-36.8 S   |
| Thrombin Time            | Report                                                                                                 | 13.9 S        |
| Thrombin Time            | Confidence Interval*                                                                                   | 11.1-16.7 S   |
| Fibrinogen**             | 200 - 400 mg/dL                                                                                        | 308           |
| Fibrinogen**             | Confidence Interval*                                                                                   | 262-354 mg/dL |

For in-vitro diagnostic use.

\* Calculated from recovered values. Actual values recovered in the user laboratory will depend on reagent lot number, instrument and technique in use. Each laboratory should establish ranges using instrument, reagent and technique in place.

\*\* Clauss fibrinogen

All individual donor units comprising this lot of Coagulation Control Plasma have been tested and found nonreactive for HBsAg and negative for antibodies to HIV and HCV. As with all blood products, this product should be handled as potentially infectious biological material.



Quality Representative

Date: 2017-10-27