



[Date]

Contents:

INTRODUCTION

- 1.1 BACKGROUND
- 1.2 AIM
- 1.3 USER REQUIREMENTS (URS) OF NEW INSTRUMENTS
- 1.4 VERIFICATION PLAN
- 1.4.1 STATISTICS USED

RESULTS

- 2.1 DESIGN QUALIFICATION
- 2.2 INSTALLATION QUALIFICATION
- 2.3 OPERATIONAL QUALIFICATION
 - 2.3.1 INTERNAL ANALYSER CALIBRATION
 - 2.3.2 IMPRECISION ANALYSIS
 - 2.3.3 LINEARITY ANALYSIS
 - 2.3.4 RANGE INCLUDING LIMIT OF DETECTION AND LIMIT OF QUANTITATION
 - 2.3.5 TEMPERATURE MAPPING
 - 2.3.6 COMPUTERISED SYSTEM
- 2.4 PERFORMANCE QUALIFICATION
 - 2.4.1 MEASUREMENT UNCERTAINTY
 - 2.4.2 METHOD COMPARISON
 - 2.4.3 MEASUREMENT ACCURACY AND BIAS
 - 2.4.4 DIAGNOSTIC SENSITIVITY AND SPECIFICITY
 - 2.4.5 TESTING
- 3. PERIODIC REVIEW
- 4. INTER-/INTRA-LABORATORY COMPARISON
- 5. CONCLUSION
- 6. CLINICAL SIGN OFF

QUANTITATIVE LABORATORY VALIDATION SUMMARY REPORT FORM

Thrombin Generation using revised
Tissue factor concentrations on
cancer VET patients

Sample only