

## CoaguChek Outpatient Clinic: Form A - Patient Training Competency Validation:

Initial Training       Follow up Visit

|   |  |  |
|---|--|--|
| <b>Patient at Home Use</b><br><br>Three comparisons performed to validate acceptable performance. Results are within:<br>+/- 0.2 @ < 3.5 PT INR - acceptable<br>+/- 0.3 @ ≥ 3.5 PT INR - acceptable | <b>Quality Control PTINR Level 1</b><br>Date: _____ (patient meter)<br>QC Range: _____<br>Lot #: _____ Exp: _____<br>Result: _____ | <b>Patient Name:</b> _____<br><br><b>Unit #:</b> _____<br><br><b>Date of birth (dd.mm.yy):</b> _____ |
|---|--|--|

| Patient Test Comparison |      |      |                     | Clinic or Lab CoaguChek XS or XS Plus |            |     |      |     | Patient CoaguChek XS |            |     |      | COMMENTS<br>Clinic Use | LIS LABEL                          |              |
|-------------------------|------|------|---------------------|---------------------------------------|------------|-----|------|-----|----------------------|------------|-----|------|------------------------|------------------------------------|--------------|
| #                       | Date | Time | LIS Request Entry # | Serial Number                         | Test Strip |     |      | INR | Serial Number        | Test Strip |     |      | INR                    | +/- 0.2 @ < 3.5<br>+/- 0.3 @ ≥ 3.5 | LAB USE ONLY |
|                         |      |      |                     |                                       | Lot        | Exp | Code |     |                      | Lot        | Exp | Code |                        |                                    |              |
| 1                       |      |      |                     |                                       |            |     |      |     |                      |            |     |      |                        |                                    |              |
| 2                       |      |      |                     |                                       |            |     |      |     |                      |            |     |      |                        |                                    |              |
| 3                       |      |      |                     |                                       |            |     |      |     |                      |            |     |      |                        |                                    |              |
| 4                       |      |      |                     |                                       |            |     |      |     |                      |            |     |      |                        |                                    |              |

**Comments - Patient CoaguChek XS capillary puncture to the Clinic CoaguChek XS or Laboratory CoaguChek XS Plus.**

A – Acceptable    B – Borderline acceptable    C – Out of range: Not approved for use of CoaguChek XS meter until further training.

Results reviewed by Hematopathologist / Designate: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Comments: \_\_\_\_\_

**REFERENCES:**

- CoaguChek® XS Operator Manual, Roche Diagnostics GmbH D-68298 Mannheim, Germany 2009-11
- CoaguChek® XS Plus Operator Manual, Roche Diagnostics GmbH D-68298 Mannheim, Germany 2009-11
- CoaguChek® XS PT Test Strip Directional Insert, Roche Diagnostics, 201 Boul, Armand-Frappier, Laval, Quebec, H7V 4A2 Canada 2010-05

## REVISION & APPROVAL LOG

| Version | Revision Type | Description of Change   | Revision Date | Technical Approval | Medical Approval        |
|---------|---------------|---|---------------|--------------------|-------------------------|
| 1.0     |               | New document  |               | Elvira Kozak       | Dr. Cathy Halstead      |
| 1.1     | Minor         | Revision  | 28 May 2014   | Elvira Kozak       |                         |
| 1.2     | Minor         | Document title and number change.<br>Upload to QMS document control | 28 Dec 2016   |                    | Dr.<br>Benjamin<br>Jung |
|         |               |   |               |                    |                         |

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