APPENDIX

EQALM POCT project:

External Quality Assessment of Point-of-Care Prothrombin Time testing in Europe

Dear EQALM member

Thank you for participating in this project. The aim is to investigate how the different EQA programs for POCT PT INR in the European countries are organized.

We kindly ask you to answer the questionnaire on the following pages and return it to anne.stavelin@noklus.no **within 15th of April**. In addition, we ask you to send a result report from your program(s).

Some of you may have more than one EQA program for POCT PT INR (e.g. one program for CoaguChek XS and CoaguChek XS Plus, one for Hemochron Jr. Signature and ProTime, and one for patient self-testing). Therefore, we have formulated the questionnaire in a way that you can answer the questions for each of the programs separately.

The questionnaire consists of three parts (blue headings). 1) The first small part is about who you are. 2) The second part has some general questions regarding all of your POCT PT INR programs, and consists of four (green) subheadings. 3) The third part contains questions about the specific POCT PT INR programs, and you have the possibility to answer the questions for four different programs (green headings). Note that the questions for program 1 to 4 are exactly the same. If you have more than four POCT PT INR programs, please contact me and I will send you another questionnaire.

The questions in part three focus on the classical EQA approach (i.e. distribution of control samples to the participants at certain time intervals). If you have an alternative approach (i.e. distribution of a set of samples with certified INR values, or comparison testing with a standard laboratory method (split sample)), please describe this approach and answer the questions that you find relevant.

Please do not hesitate to contact me if you have any questions.

Best regards

Anne Stavelin, NOKLUS (study coordinator)
Piet Meijer, ECAT
Dianne Kitchen, UK NEQAS BC
Sverre Sandberg, NOKLUS

1. Information about the EQA organisation

EQA organisation:

Country:

Contact person:

e-mail and telephone:

2. General questions about the POCT PT INR programs

Participation and consequences

2.1. Is it mandatory or voluntary to participate in the POCT PT INR program?

❑ Mandatory ❑ Voluntary

2.2. Do unacceptable results have consequences for the participants? (e.g. no reimbursement, close down of the laboratory)

❑ No ❑ Yes If yes, please specify: _____

Target value and acceptability limits

2.3. What kind of target value do you use?

❑ Reference method value ❑ Overall mean/median value ❑ Method group mean/median value ❑ Other, specify: _____

2.4. Do you exclude outliers before calculating the mean or median value?

❑ Yes ❑ No ❑ We do not calculate the mean or median value

2.5. Do you exclude *other results* before calculating the mean or median value? (e.g. deviating results from a specific reagent lot number)

❑ No ❑ Yes If yes, please specify: _____

2.6. What are the acceptability limits? (e.g. results within ± 15% of the target value)

Supervision and guidance of the participants

2.7. Do you have some criteria for contacting the participants for guidance?

❑ No ❑ Yes If yes, please specify: _____

2.8. If you have some contacts with your participants (except from the user meetings), is it mainly you or the participants who make the contact?

❑ It is mainly we who contact the participants ❑ It is mainly the participants that contacts us ❑ There is equal contact both ways

2.9. How much time do you spend on guiding the participants? (state the approx. average in a year)

❑ Less than 1 hour a week ❑ 1-8 hours a week ❑ 1-2 days a week ❑ More than 2 days a week

2.10. How do you supervise and guide the participants?

❑ By telephone ❑ By e-mail ❑ Visits ❑ On participant meetings

❑ Other, specify:_____

2.11. How many participant meetings do you offer in a year?

Participants from other countries

2.12. Can other countries participate in your POCT PT INR program(s)?

❑ Yes ❑ No

2.13. If yes, which countries and how many participants?

Country	Number

3. Questions about the specific POCT PT INR programs

Please answer the questions for each POCT program separately. If you offer a POCT program with an "alternative" approach, please answer the below questions that are relevant for this approach.

Program 1.

3.1. Please fill in the tables below (Which and how many POCT devices are included in this program? What type of participants and how many?)

POCT devices in this program	Number of participants
❑ CoaguChek S	
❑ CoaguChek XS	
❑ CoaguChek XS Plus	
❑ Simple Simon	
❑ Thrombotrack	
❑ Hemochron Jr. Signature	
❑ ProTime	
❑ Avosure	
❑ I-Stat	
❑ INRatio	
❑ Other, specify:	

Type of participants	Number of participants
❑ Patients	
❑ General practitioners	
❑ Hospital clinics	
❑ Nursing homes	
❑ Pharmacies	
❑ Thrombose clinics	
❑ Other, specify:	

3.2. What type of control material do you use in this program?

❑ Fresh frosen plasma ❑ Lyophilized plasma ❑ Lyophilized whole blood ❑ Other, specify: _____

3.3. Do you produce the control material yourself?

❑ Yes ❑ No

3.4. If no, please specify where you obtain the samples (e.g. from manufacturers or EQA organizers)

3.5. How many control samples do you distribute per survey?

3.6. How many measurements do you recommend per sample?

❑ Single measurement ❑ Duplicat measurements ❑ Other, specify: _____

3.7. How frequently do you distribute the control samples to the participants?

❑ Once a year ❑ Twice a year ❑ Four times a year ❑ Six times a year ❑ Other, specify: _____

3.8. What do you distribute *in addition* to the control samples?

❑ Nothing ❑ Destillated water ❑ Calcium chloride ❑ Pipettes ❑ Other, specify: _____

3.9. What are the participants' deadline for reporting results (in days)?

3.10. If this program has an "alternative" EQA approach, please describe this approach.

Please attach a anonymised result report from this program

Program 2.

3.1. Please fill in the tables below (Which and how many POCT devices are included in this program? What type of participants and how many?)

POCT devices in this program	Number of participants
❑ CoaguChek S	
❑ CoaguChek XS	
❑ CoaguChek XS Plus	
❑ Simple Simon	
❑ Thrombotrack	
❑ Hemochron Jr. Signature	
❑ ProTime	
❑ Avosure	
❑ I-Stat	
❑ INRatio	
❑ Other, specify:	

Type of participants	Number of participants
❑ Patients	
❑ General practitioners	
❑ Hospital clinics	
❑ Nursing homes	
❑ Pharmacies	
❑ Thrombose clinics	
❑ Other, specify:	

3.2. What type of control material do you use in this program?

❑ Fresh frosen plasma ❑ Lyophilized plasma ❑ Lyophilized whole blood ❑ Other, specify: _____

3.3. Do you produce the control material yourself?

❑ Yes ❑ No

3.4. If no, please specify where you obtain the samples (e.g. from manufacturers or EQA organizers)

3.5. How many control samples do you distribute per survey?

3.6. How many measurements do you recommend per sample?

❑ Single measurement ❑ Duplicat measurements ❑ Other, specify: _____

3.7. How frequently do you distribute the control samples to the participants?

❑ Once a year ❑ Twice a year ❑ Four times a year ❑ Six times a year ❑ Other, specify: _____

3.8. What do you distribute *in addition* to the control samples?

❑ Nothing ❑ Destillated water ❑ Calcium chloride ❑ Pipettes ❑ Other, specify: _____

3.9. What are the participants' deadline for reporting results (in days)?

3.10. If this program has an "alternative" EQA approach, please describe this approach.

Please attach a anonymised result report from this program

Program 3.

3.1. Please fill in the tables below (Which and how many POCT devices are included in this program? What type of participants and how many?)

POCT devices in this program	Number of participants
❑ CoaguChek S	
❑ CoaguChek XS	
❑ CoaguChek XS Plus	
❑ Simple Simon	
❑ Thrombotrack	
❑ Hemochron Jr. Signature	
❑ ProTime	
❑ Avosure	
❑ I-Stat	
❑ INRatio	
❑ Other, specify:	

Type of participants	Number of participants
❑ Patients	
❑ General practitioners	
❑ Hospital clinics	
❑ Nursing homes	
❑ Pharmacies	
❑ Thrombose clinics	
❑ Other, specify:	

3.2. What type of control material do you use in this program?

❑ Fresh frosen plasma ❑ Lyophilized plasma ❑ Lyophilized whole blood ❑ Other, specify: _____

3.3. Do you produce the control material yourself?

❑ Yes ❑ No

3.4. If no, please specify where you obtain the samples (e.g. from manufacturers or EQA organizers)

3.5. How many control samples do you distribute per survey?

3.6. How many measurements do you recommend per sample?

❑ Single measurement ❑ Duplicat measurements ❑ Other, specify: _____

3.7. How frequently do you distribute the control samples to the participants?

❑ Once a year ❑ Twice a year ❑ Four times a year ❑ Six times a year ❑ Other, specify: _____

3.8. What do you distribute *in addition* to the control samples?

❑ Nothing ❑ Destillated water ❑ Calcium chloride ❑ Pipettes ❑ Other, specify: _____

3.9. What are the participants' deadline for reporting results (in days)?

3.10. If this program has an "alternative" EQA approach, please describe this approach.

Please attach a anonymised result report from this program

Program 4.

3.1. Please fill in the tables below (Which and how many POCT devices are included in this program? What type of participants and how many?)

POCT devices in this program	Number of participants
❑ CoaguChek S	
❑ CoaguChek XS	
❑ CoaguChek XS Plus	
❑ Simple Simon	
❑ Thrombotrack	
❑ Hemochron Jr. Signature	
❑ ProTime	
❑ Avosure	
❑ I-Stat	
❑ INRatio	
❑ Other, specify:	

Type of participants	Number of participants
❑ Patients	
❑ General practitioners	
❑ Hospital clinics	
❑ Nursing homes	
❑ Pharmacies	
❑ Thrombose clinics	
❑ Other, specify:	

3.2. What type of control material do you use in this program?

❑ Fresh frosen plasma ❑ Lyophilized plasma ❑ Lyophilized whole blood ❑ Other, specify: _____

3.3. Do you produce the control material yourself?

❑ Yes ❑ No

3.4. If no, please specify where you obtain the samples (e.g. from manufacturers or EQA organizers)

3.5. How many control samples do you distribute per survey?

3.6. How many measurements do you recommend per sample?

❑ Single measurement ❑ Duplicat measurements ❑ Other, specify: _____

3.7. How frequently do you distribute the control samples to the participants?

❑ Once a year ❑ Twice a year ❑ Four times a year ❑ Six times a year ❑ Other, specify: _____

3.8. What do you distribute *in addition* to the control samples?

❑ Nothing ❑ Destillated water ❑ Calcium chloride ❑ Pipettes ❑ Other, specify: _____

3.9. What are the participants' deadline for reporting results (in days)?

3.10. If this program has an "alternative" EQA approach, please describe this approach.

Please attach a anonymised result report from this program