NOTES TO FLOWCHART FOR HANDLING DEVIATING EQA RESULTS

Note	Remark
Pre-note	The comment letter or comment section in the report may include comments regarding remarkable observations (e.g. a relative large deviation for a specific method mean with respect to the overall assigned value). Evaluate carefully the remarks and consider whether this could be explaining your deviating result.
1	The participant had made an error in recording the test result of the EQA sample(s) and as such reported a wrong result(s). This is an internal cause for the error made. The participant should carefully review the process of result recording and take appropriate action to avoid this problem in future surveys.
2	The participant had made an error in reporting the test result of the EQA sample(s) to the EQA organisation. This is an internal cause for the error made. The participant should carefully review the process of result reporting and take appropriate action to avoid this problem in future surveys.
3	The participant had mixed-up the test results either at the level of recording the test result from the instrument or when the test results were reported to the EQA organisation. The participant should carefully review the process of result recording and/or reporting and take appropriate action to avoid this problem in future surveys.
4	The participant had reported the result with the wrong unit (e.g. report the result in U/dL instead of U/mL). This may lead to incorrect treatment of the data in the evaluation software of the EQA organiser. In this case the result could be assigned as an outlier. The participant should select the correct unit when reporting a result to avoid this problem in future surveys.
5	The participant had reported the wrong method and/or equipment used. This may lead to inclusion of the result in the wrong method/equipment group. This may affect both the total evaluation of that group(s) as well as the evaluation of your own result and performance assessment. The participant should select the correct method/equipment when reporting a result to avoid this problem in future surveys.
6	The EQA provider had wrongly entered your data (e.g. result, unit, method, instrument etc.) into the database which leads to a wrong evaluation of your performance. Please inform the EQA provider and ask for an amended report.
7	The EQA provider had distributed inappropriate sample material (e.g. the sample material is not commutable for your specific method. I.e. the sample material used by the EQA provider behave for your specific method not identical as a real patient sample). This may affect your performance assessment. It is the responsibility of the EQA provider to write a note about this issues in the report or comment letter. If this is not done, please inform the EQA provider and ask for an amended report or comment letter.
8	The EQA provider had made a mistake in the labelling of the sample(s). As such the evaluation is not in correspondence with the description of the sample information and/or expected target values. It is the responsibility of the EQA provider to write a note about this issue in the report or comment letter. If this is not done, please inform the EQA provider and ask for an amended report or comment letter. In addition, the EQA provider should provide replacement of the sample to give you the opportunity to rerun the sample or the EQA provider has to rerun the whole survey.
9	You have received wrong samples because of an error in the packaging by the EQA provider. Because you was not aware of this fact you had measured the wrong samples which may had affect your performance assessment. It is the responsibility of the EQA provider to write a note about this issues in the report or comment letter. If this is not done, please inform the EQA provider and ask for new samples and an amended report. It is also the responsibility of the participant to check whether they have received the correct samples as soon as possible after receipt. If this is not done by the participant it is also the responsibility of the participant if incorrectly received samples are still measured.
10	The EQA provider selected an inappropriate manner to distribute the sample (e.g. inappropriate packaging material, distribution at an inappropriate time period, etc.). This may lead to delay in the receipt, damage of the package etc. Measuring such samples may have affected your performance assessment. Please inform the EQA provider in time about such issues in future surveys. In addition, the EQA provider should provide replacement of the sample(s) to give you the opportunity to rerun the sample and provide you with an amended report. In general, inform the EQA provider immediately after the delayed receipt of samples or when the package is damaged and sample are probably affected and ask for replacement of the sample(s).
11	The EQA provider had distributed a sample with insufficient stability. This may affect your performance assessment. It is the responsibility of the EQA provider to write a note about this issue in the report or comment letter and rerun the survey. If this is not done, please inform the EQA provider and ask to rerun the survey with better samples and provide the participants with an amended report.
12	The EQA provider had distributed a sample with insufficient homogeneity. This may affect your performance assessment. It is the responsibility of the EQA provider to write a note about this issue in the report or comment

	letter. If this is not done, please inform the EQA provider and ask for an amended report or comment letter. In addition, the EQA provider should provide replacement of the sample(s) to give you the opportunity to rerun the sample and provide you with an amended report.
13	The EQA provider had provided inappropriate information in the instruction letter. Because of this you may have not handled the sample in an appropriate way. This may have affected your performance assessment. It is the responsibility of the EQA provider to write a note about this issues in the report or comment letter. If this is not done, please inform the EQA provider and ask for an amended report or comment letter. In addition, the EQA provider should provide replacement of the sample(s) to give you the opportunity to rerun the sample and provide you with an amended report.
14	The participant is informed by the EQA provider about the dispatch date of the samples (e.g. by an annual survey schedule). There is a delay in the delivery of the samples in your laboratory. This may be caused for instance by wrong information available by the EQA provider about the address details or wrong distribution within the hospital. This may lead to bad test results. Please evaluate carefully the delivery and/or distribution of the samples and take appropriate action to avoid this problem in future surveys. If there is a systematic delay in the delivery of the sample (e.g. because of the post services in for in your particular country), the EQA provider should be informed and another way of delivery of the samples should be used (e.g. courier service).
15	Samples were not stored in a proper way after receipt. For instance they were not put into the refrigerator. This may lead to bad test results. Please evaluate carefully the procedure for storage of the samples and take appropriate action to avoid this problem in future surveys.
16	The samples were not reconstituted in a proper way because, for instance, you did not use calibrated pipettes. Therefore you pipette the wrong volume. Another possibility is that you did not mix the sample properly. This may lead to bad test results. Please evaluate carefully the procedure for reconstitution of the samples and take appropriate action to avoid this problem in future surveys.
17	You have not read the instruction letter carefully. Therefore you may have made a mistake in the handling of the sample (for example: the sample used in this survey was stable for a shorter time period as usual and you did not notice this. Therefore you did not measure the sample within the stable time period). This may lead to bad test results. Please read carefully the instruction letter every time.
18	If the manufacturer has made changes in the test constitution and/or procedure they should have made the user aware of this. If this is not done the manufacturer should be informed and asked for improved communication in future cases. The laboratory should evaluate/validate the revised test procedure and adapt the test procedure when necessary. If the laboratory has not changed the test procedure based on information given by the manufacturer, internal actions have to be carried out.
19	If there was any problem related to the equipment at the time the EQA samples were measured, (e.g. problems due to maintenance issues, calibration, test settings) internal actions have to be carried out to prevent repeated problems.
20	If there was any problem related to the reagents used at the time the EQA samples were measured, (e.g. problems with a specific lot. no., reconstitution, storage) actions have to be carried out to prevent repeated problems. If the problem is caused by external factors the distributor or manufacturer of the reagents should be contacted.
21	If there was any problem related to the performance of the test at the time the EQA samples were measured, (e.g. test settings, local modifications, calibration) internal actions have to be carried out to prevent repeated problems.
22	If the results of the internal quality control samples could explain the deviation of the EQA results, internal actions have to be carried out to prevent repeated problems. Make sure that the patient results were correct during the period the EQA samples were measured. Look for trends in internal quality control results.
23	It is the responsibility of the EQA provider to provide the participant with information about the statistical procedure used (e.g. information included in each report or provided on an annual basis in a survey manual). Review whether there was maybe a problem with the statistical method used for this particular data set, e.g. due to a non-normal distribution of the results or the size of the data set. Contact the EQA provider and ask for further explanation by the EQA provider.
24	If the assigned value (AV) was established by a reference method the deviation might be caused by either the assignment of the AV or your method. Check the deviation of other methods used. If the deviation is similar to your method the AV might be incorrect. Inform the EQA provider. If the deviation is not similar to other methods, analyse reference material and some patient samples in parallel with another reliable method. Make the manufacturer of your method aware of the deviation. Ask for appropriate action. If the AV is a consensus value (calculated from all the results in a method group consisting of different methods) and the deviation is representative for your method, realise that the AV of the total group is not representative for your method. The laboratory should evaluate their EQA results to the method specific consensus value and not to the AV of the total group. If the method specific AV is not given in the report ask the EQA provider for possibilities to provide

	this information. If the AV is calculated from a small number of results this might result in a less reliable AV. Interpret the result carefully. If the AV is not calculated from original results but from a mix of original and modified results (e.g. by the use of a local correction factor), this might contribute to a large variation and an incorrect AV. When reporting results it should be possible to mark if the results are not original and as such should be excluded from the assignment of the AV or treated as a separate method group (in the case sufficient participants use the same modification of results).
25	The EQA provider had probably wrongly presented the results in the report (e.g. results for your specific method are linked to another method.). Please inform the EQA provider and ask for an amended report.
26	A similar deviation has been observed earlier. If the deviation is typical for the method the cause is external [see notes 18 (e.g. change in method) and 20 (e.g. problem with specific lot of reagents)]. The cause can also be due to the EQA samples used (e.g. non-commutable for a particular method). If not, the cause is internal. Make sure that the internal quality control and patient results were correct at the time the EQA samples were measured. Undertake appropriate corrective actions.
27	If relevant, complain the EQA organiser that the sample material used in the survey was probably inappropriate for your method. Some materials show especially large variation for one specific method and in that case the deviation might be large compared to your acceptable limits without being large compared to the variation for your method. Inform EQA organiser and ask for the use better commutable material (when possible).
28	When multiple samples with different concentration were used, investigate thoroughly if a systematic error is present. A systematic error may have different sources, e.g. problems with the calibrator (external), pipetting error (internal), problems with a certain lot no of the reagents used (external), problem with the value assignment (external). The potential cause should be investigated thoroughly and appropriate actions should be undertaken.
29	Repeat analysis on stored EQA material. If the repeat analysis shows no deviation anymore the method seems to be OK. Make sure that the internal quality control and patient results were correct at the time the EQA samples were measured. When necessary undertake appropriate corrective actions. If repeat analysis shows the same deviation ask the EQA organiser for a repeat sample(s) for re-analysis. If the repeat analysis show no deviation anymore the method seems to be OK. There was most likely something wrong with the EQA sample (e.g. wrong sample sent by EQA organiser, pipetting error during reconstitution). If repeat analysis show the same deviation there seems to be, for instance, something wrong with the method used (external cause) or with the sample sent by the EQA organiser (external cause). Investigate thoroughly potential causes and undertake appropriate actions.
30	Reconsider whether the acceptance limits is relevant for the parameter under investigation. If the limits are expressed in %, they are probably not suitable for the lowest concentration of the analyte (the measurement uncertainty will be larger than the acceptable limit if the concentration/activity is low). When high concentrations are less important the deviation for high sample are even less important (from an analytical point of view, it might be worth reducing the error).