

Title European follow-up of incorrect biomarker results for colorectal cancer demonstrates the importance of quality improvement projects.

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File **Supplemental Table 2: Overview of definitions for the error categories available in the survey and examples reported by respondents.**

Category	Included criteria	Real life examples from survey respondents
Pre-analytical phase	Sample reception, sample identification, sample preparation: deparaffinization, H&E staining, micro/macrodisection, selection of neoplastic cell region by pathologist, scraping of the tissue	
Analytical Phase	DNA extraction, library preparation, mutation analysis according to pre-determined protocol	
Post-analytical phase	Readout of the analytical results, interpretation of the samples according to predetermined criteria, clinical interpretation, communication of results , entering of the results in the laboratory information system/EQA datasheet	
Clerical error	Sample processed correctly, but results were incorrectly entered into the EQA datasheet or the laboratory's own information system/miscommunication between departments.	<ul style="list-style-type: none"> <li>▪ Mistake by manually entering the result into the online datasheet</li> <li>▪ Result was negative but was incorrectly reported as positive</li> </ul>
Interpretation error	Sample processed correctly, but incorrect conclusions are made from the output of the test.	<ul style="list-style-type: none"> <li>▪ Mutated peak was closer to the positive control in a WT case</li> <li>▪ Artefact substitution (G&gt;A) in a hotspot was considered as a true mutation</li> <li>▪ Incorrect filter applied to the variant list</li> </ul>
Methodological problem	Problems that occur because the method is not optimally suited for all situations presented at the laboratory.	<ul style="list-style-type: none"> <li>▪ Variant of the gene was not detected by the kit for unknown reasons</li> <li>▪ Gene variant was not included in the kit or frequency was below limit of detection</li> <li>▪ Occasional problem with reporting of low frequent variants by the method</li> </ul>
Personnel error	Error that occurred due to a mistake of the personnel (besides clerical errors).	<ul style="list-style-type: none"> <li>▪ Specimen mix-up</li> <li>▪ Pipetting error during PCR</li> <li>▪ Probably contamination by another sample</li> <li>▪ Rare variant, clinical significance overseen in output due to time pressure</li> </ul>
Problem with tissue material	Problems that are caused because the EQA material differs from material used for validation of the method.	<ul style="list-style-type: none"> <li>▪ Insufficient amount of library and subsequently, insufficient coverage</li> <li>▪ Fragmented DNA</li> <li>▪ No efficient amplification of the PCR product</li> </ul>
Reagent problem	Unexpected problems that occur with reagents for the analysis.	<ul style="list-style-type: none"> <li>▪ Suspected reagent problem in commercial kit (not further specified)</li> </ul>
Technical problem	A technical problem occurred with the available hardware/software present in the laboratory.	<ul style="list-style-type: none"> <li>▪ Heat-plate for annealing was not calibrated well</li> <li>▪ Analysis error in the used software plug in</li> <li>▪ Sequencer unable to analyze the sequence because the DNA template was not good enough</li> </ul>