

# LABQUALITY DAYS

## New quality indicator scheme for the laboratory process in pathology

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### Introduction

Equalis provides over 100 external quality assessment (EQA) schemes and has offered EQA within pathology since 1998. As a complement to traditional EQA schemes, Equalis offer quality indicator schemes. In these schemes, laboratories report their results from the previous production year, allowing them to compare their performance with other laboratories in Sweden and identify potential diagnostic issues. In 2023, in collaboration with the KVASt (quality and standardization committee) group for the laboratory and preanalytical process, Equalis launched a pilot round for a quality indicator scheme within the laboratory and preanalytical process, which then became an annual EQA scheme in 2024.

### Aims

The aim of this scheme is to enhance patient safety by standardizing the handling of patient samples, achieved through statistical comparisons and continuous evaluation of quality indicators within the laboratory and preanalytical process. Additionally, the scheme seeks to raise awareness of critical steps in the laboratory and preanalytical process and provide laboratories with knowledge of key parameters to document in their laboratory information system (LIS).

### Methods

The quality indicators in the scheme are derived from the KVASt document “Kvalitetsdokument för preanalytisk hantering, kvalitetssäkring och optimering av den histopatologiska labprocessen” (Quality document for the preanalytical handling, quality assessment and optimization of the histopathology lab process), published in 2022 (1). This Swedish recommendation is based on the publication of Compton CC. et al published in 2019 (2) and European consensus recommendations from Clinical and laboratory standards institute from 2011 (3).

In the scheme, the participants are asked yes/no questions about guidelines or routines for specific steps in the laboratory process and to provide numerical data on sample handling. They also estimate the completeness of their reported data on a scale from 1 (not available in their LIS) to 5

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(all data easily accessible). All Swedish histopathology laboratories were invited to participate in the pilot round in 2023 and in the official scheme that started in 2024.

After each round participants received three reports: one with their own yes/no question results, one with the numerical data as percentages with a 95% confidence interval, and one with comments from the KVASt group.

## Results

In the pilot round of 2023, 20 laboratories participated, and in 2024, 19 participated.

All participants answered the yes/no questions in both rounds. In 2023, 19/20 laboratories reported numerical results, and in 2024, all 19 reported numerical results. However, in neither round did all laboratories answer all the numerical quality indicators.

The median completeness score was 2 and the mean was 2.8 in 2023. In 2024, both the median and the mean increased to 3.

## Conclusions

The implementation of the quality indicator scheme for the laboratory process has highlighted the challenges laboratories face in extracting precise numerical data from their LIS. Despite these difficulties, data accessibility improved slightly between rounds. It is crucial for laboratories to continuously track their own development and benchmark their performance against other laboratories to identify areas of improvement. Ongoing participation and feedback will be essential as the scheme evolves and supports the enhancement of the preanalytical process.

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1 Askerlund A, Rännar L, Gabrielsson P, Nordström U, Andersson E, Green J. Kvalitetsdokument för preanalytisk hantering, kvalitetssäkring och optimering av den histopatologiska labprocessen. 2022

2 Compton CC, Robb JA, Anderson MW, Berry AB, Birdsong GG, Bloom KJ, Branton PA, Crothers JW, Cushman-Vokoun AM, Hicks DG, Nowak JA, Olson D, Pfeifer JD, Schade A, Vance GH, Walk EE, Yohe SL. Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine. 2019, Vol. 143(11):1346-1363, ss. 1353–1356.

3 Clinical and Laboratory Standards Institute. Quality assurance for design control and implementation of immunohistochemistry assays; Approved Guideline-Second addition. 2011.