RESULTS OF QUALITY CONTROL IN PATHOLOGY THROUGH THE EXTERNAL QUALITY ASSESSMENT PROGRAM IMPLEMENTED IN VIETNAM DURING THE PERIOD 2021-2025

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ABSTRACT

External quality assessment (EQA) is an important tool to control quality tests. In the period from 2007 to 2025, the Center for standardization and quality control in medical laboratory (CSQL) has continuously developed and implemented a wide range of EQA programs, ranging from routine to specialized schemes, with the aim of supporting laboratories in improving testing quality. The number of laboratories participating in EQA by CSQL has rapidly increased from 50 participants (2007) to 3,800 participants (2025). The Pathology EQA program has been implemented since 2021. After five years of implementation, Pathology laboratories have shown increasing attention in participation as part of their effort to enhance analytical quality at their institutions.

This study aims to evaluate the quality control results of pathological examination in the period 2021-2025 through data analysis from the Pathological EQA Program implemented by CSQL. This study is based on EQA data collected from all Pathology laboratories participating in the program. The main indicators reflecting the quality control results include number of participants, number of histopathologies analyzed and evaluated the proportion of acceptable analytical results and frequency of recorded errors types (e.g. diagnostic errors, technical errors). The data were analyzed using descriptive statistics and trend analysis methods.

The research results show that the number of Pathology Departments nationwide participating has increased every year since 2021 with 09 Pathology Departments participating, increasing to 40 Pathology Departments participating in 2025. The percentage of participating hospital models

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including specialized hospitals 39%, general hospitals 39%, private general hospitals 11% and private laboratories 11%. The number of histopathology groups evaluated increased from 7 to 18 different tissue groups including general and specialized fields, the number of samples (number of cases) analyzed is 18 (in 2021) increased to 156 cases (in 2025). Statistics show that some types of tissues are commonly deployed according to the model and characteristics of each Pathology laboratory (including stomach, gastric biopsy, uterus, breast, thyroid, colon, liver, lung, brain,...).

Keywords: External quality assessment, pathology, quality assurance.

1. INTRODUCTION

Pathology plays a fundamental role in modern medicine by providing definitive diagnoses for a wide range of diseases, particularly malignancies, thereby guiding appropriate treatment strategies. Due to its complexity and high level of expertise required, ensuring quality in pathology testing is essential to prevent diagnostic errors and inappropriate clinical decisions.

Quality in pathology is evaluated based on three key criteria: accuracy, timeliness, and completeness of diagnostic reports [1]. Errors in any of these aspects may lead to serious consequences, including misdiagnosis, delayed treatment, and increased mortality risk [1]. Quality management in pathology requires a comprehensive approach covering all phases of the testing process: Pre-analytical errors: patient misidentification, incorrect specimen site, specimen loss, non-representative samples, insufficient clinical information, Analytical errors: false positive/negative results, incorrect classification (benign vs malignant), grading errors, Post-analytical errors: incomplete or incorrect reports, transcription errors. Therefore, quality management must focus not only on minimizing random errors but also on detecting and preventing systematic technical and interpretative errors that may directly impact patient outcomes.

The Center for Standardization and Quality Control in Medical Laboratory (CSQL) is the first institution in Vietnam to implement a national EQA program in pathology, alongside international providers such as UK NEQAS, CAP, Labquality, and the Royal College of Pathologists. After five years of implementation, this study was conducted to evaluate the effectiveness of pathology quality management through the national EQA program and to provide direction for further improvement.

2. MATERIALS AND METHODS

2.1. Materials

The study included all EQA data from pathology laboratories participating in the program from 2021 to 2025.

Collected information included: hospital name, laboratory identification code (anonymized), facility type (specialized or general hospital), and ownership (public or private).

All case-related data and EQA slides were anonymized according to the program's confidentiality procedures.

2.2. Methods

This study employed a retrospective, descriptive cross-sectional method to analyze the results of the EQA GPB program implementation nationwide from 2021 to 2025.

Data were continuously collected from the management system of the Center. All administrative and specimen data were anonymized.

Outcome indicators included number of participating laboratories, number of EQA rounds, laboratory classification, number of samples evaluated, proportion of acceptable results, and frequency of errors.

Diverse models: The EQA program closely followed the disease patterns at PGPB, helping to keep quality management focused and aligned with actual needs

2.3. Evaluation framework and Acceptance Criteria

Evaluation criteria: EQA results were evaluated by a panel of experts on a scale of 0-5 for each evaluation category, including: technique (tissue preparation, tissue fixation, cutting, staining, and complete slide preparation) and diagnostic evaluation (accuracy of diagnosis and interpretation of results).

Table 1: Outpatient evaluation framework for the external audit program

Content evaluation	
Technical evaluation	**Diagnostic evaluation**
Sufficient tissue quantity as described macroscopically	No results
The section is positioned between the slides, without wrinkles, folds, or tissue tears	Results lacking microscopic description or inconclusive disease findings
The lamination completely covers the cut piece, with no air bubbles	The microscopic description and diagnosis are inappropriate
The cut pieces have the appropriate thickness and absorb color evenly	The microscopic description and pathological conclusions do not fully match the tissue sample
The nuclear and cytoplasmic components stain correctly, and the nuclear membrane and chromatin are clearly visible	The microscopic description and pathological findings are entirely consistent with the tissue sample
Sufficient tissue quantity as described macroscopically	The microscopic description and pathological findings are entirely consistent with the tissue sample and include reasonable recommendations

This evaluation standard references the quality control requirements of ISO 15189 and framework evaluation references from international EQA organizations (CAP, UK NEQAS).

The unit of analysis was individual cases. The aggregated results were calculated per case, summarizing general data for each period and cycle (year) of each PGPB and the overall statistical results of the program.

2.4. Expert panel and standard answer development process

Establishing a "gold standard": The gold standard was developed through a consensus consultation by a panel of experts based on original specimens and clinical data. The expert panel consisted of pathology specialists from central and provincial/city hospitals with extensive professional experience and was selected by the

science and technology council of the Center for Clinical Laboratory Technology. The expert panel was established according to Decision No. 91/ QD-KCXN dated April 16, 2024, and Decision No. 212/QD-KCXN.

Each specimen was independently scored by at least three members of the expert panel. If consensus was not reached, the specimen was sent for further consultation.

Specimens submitted to the expert panel were fully encrypted (using a coding process to anonymize participating pathology laboratories) to ensure objectivity. The study used encrypted and anonymized secondary administrative data. The reported results were based solely on aggregated data.

2.5. Data collection and statistical analysis of results

He evaluation results were continuously monitored from the first year of implementation (2021) to 2025.

Data was calculated using Excel 2010 software.

3. RESULTS AND DISCUSSION

3.1. Number of laboratories participating in external quality control over the years

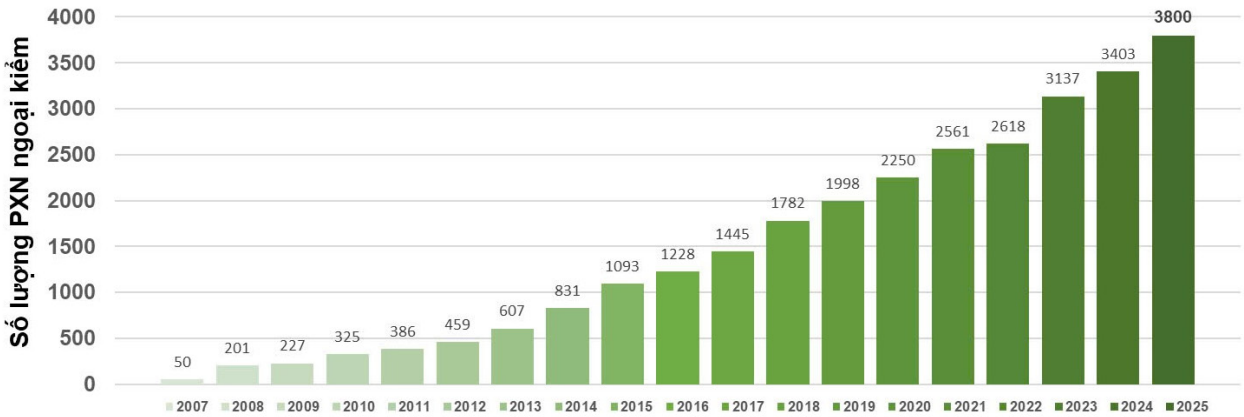

Figure 1: Total number of laboratories participating in EQA programs at CSQL (2007-2025)

Statistics show that the focus on quality management in laboratory testing, from routine to specialized, has increased over the years, from 50 laboratories (in 2007) to 3.800 laboratories (in 2025).

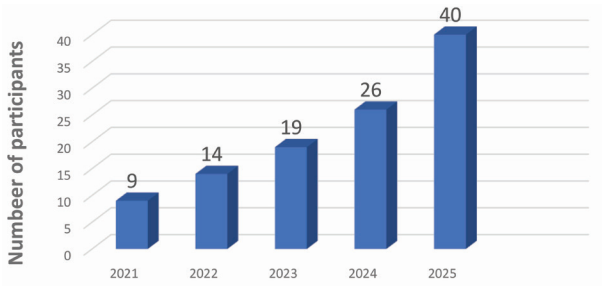

Figure 2: Number of Pathology labs participating in external audits over the years

Research on the implementation of external quality control shows an increase in the number

of participating laboratories in the external quality control program, from 9 laboratories (in 2021), the first year the Center for Laboratory Quality Control officially implemented the program, to 40 laboratories (in 2025). This continuous upward trend reflects the interest of healthcare facilities in quality control of laboratory testing and confirms the effectiveness of the external quality control program for laboratories.

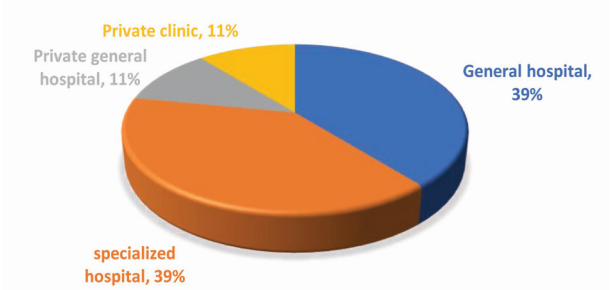

Figure 3: Statistics of hospitals/laboratories participating in the EQA pathology

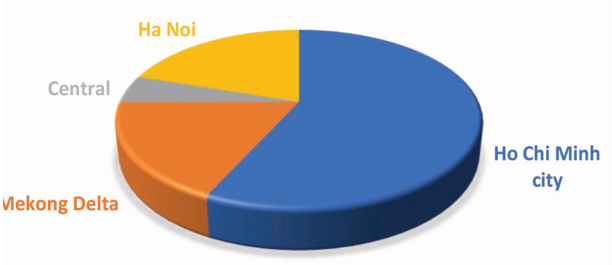

Figure 4: Geographical distribution of hospital/ laboratories participating in the EQA pathology

Geographic distribution statistics show that the majority of participating laboratories are concentrated in 3 regions Ho Chi Minh city: 57%; Ha Noi city: 20%; Mekong Delta: 18%; behide 5% participants in central.

3.2. Statistical analysis of the quantity and characteristics of histopathological tissues in external quality assessment

Table 2: Statistics on the number and types of tissues subjected to external quality assessment over the years

2021		2022		2023		2024		2025	
Tissue	**Quantity**	**Tissue**	**Quantity**	**Tissue**	**Quantity**	**Tissue**	**Quantity**	**Tissue**	**Quantity**
Colon	7	Colon	8	Uterus and ovaries	12	Lung tissue	13	Stomach biopsy	20
Breast tissue	5	Thyroid gland	8	Breast tissue	8	Stomach	11	Stomach	18
Stomach-biopsy	2	Breast tissue	8	Lung	8	Liver tissue	11	Uterus	18
Thyroid gland	1	Ovaries	7	Stom-ach biopsy	7	Cervix	9	Ovaries	16
Stomach polyps	1	Brain tumor	5	Brain tumor	6	Kidney	7	Liver tissue	12

2021		2022		2023		2024		2025	
Tissue	**Quantity**	**Tissue**	**Quantity**	**Tissue**	**Quantity**	**Tissue**	**Quantity**	**Tissue**	**Quantity**
Colon polyps	1	Stomach biopsy	4	Colon	5	Breast tumors	7	Thyroid gland	12
Appendix	1	Prostate gland	3	Prostate gland	4	Ovaries	6	Kidney tissue	10
-	-	Bladder	2	Bladder	3	Stomach	6	Lung tumors	10
-	-	Lung	2	Liver tissue	3	Colon	6	Stomach	8
-	-	Gallbladder	2	Thyroid gland	3	Brain tumor	6	Colon	8
-	-	salivary glands	2	Kidney	2	Thyroid gland	3	Colon	6
-	-	Stomach	1	Gallbladder	2	Cervical lymph nodes	2	Stomach	4
-	-	Colon polyps	1	Salivary glands	2	Nasal tumor	2	Breast tissue	4
-	-	Gallbladder	1	Nasal tumor	2	Jaw angle region	1	Testis	2
-	-	Jaw angle region	1	Jaw angle region	1	Submandibular gland	1	Prostate gland	2
-	-	-	-	Brain	1	Salivary glands	1	Nasal tumor	2
-	-	-	-	Larynx	1	Prostate gland	1	Brain tumor	2
-	-	-	-	Submandibular gland	1	Nasopharynx	1	Bone tumor	2

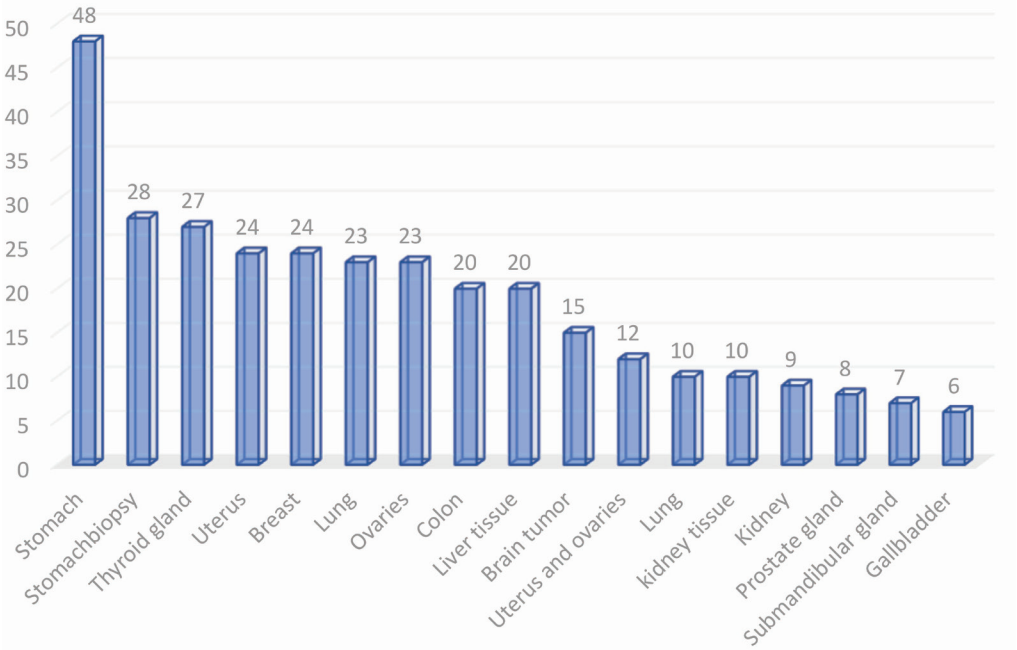

Figure 5: Statistics of the most frequently deployed tissue types over 5 years

The external quality control program for tissue samples at the CSQL was implemented with a focus on disease patterns and aligns with the list of procedures currently being performed by the tissue sample processing units. Therefore, the diversity of tissue types performed over the years is evident (Table 1), and the tissue types most frequently subjected to external quality control by the tissue sample processing units over the past five years are shown (Figure 4). This demonstrates that the external quality control program has met the needs for quality control of the techniques performed by the tissue sample processing units, focusing on the correct techniques and aligning with the list of techniques being implemented at the unit, thus improving diagnostic work at the unit.

Case distribution and difficulty level (malignant/benign): In the total number of cases (18 cases in 2021 to 156 cases in 2025), the proportion of malignant/benign cases was balanced to ensure representativeness of the practical work of the clinical Pathology Laboratories. Specifically, the proportion of malignant cases (e.g., Carcinoma 39) is maintained at 30-40% of the total cases annually, with the remainder being benign tumors, sarcomas, or other pathologies. The proportion of cases requiring staging or difficult diagnosis is maintained at 15-20% to challenge the Pathology Laboratories, as reflected in the number of Carcinoma cases evaluated. The distribution of pathologies or case difficulty levels will be adjusted over time depending on the number of participants in the program and quality improvements through annual external quality control data.

3.3. Results of external audits over the years

To comprehensively evaluate the performance of the Pathology Laboratories, the approach includes all three stages of the testing process,

from the technical preparation of specimens to the analysis and reporting of results. The study showed that the external quality control results over the five years of the participating pathology laboratories were relatively good.

Table 3: Statistics on the implementation results of the pathology laboratories over 5 years

		2021	2022	2023	2024	2025
Results of implementation	Acceptable results	100%	100%	99%	100%	99%
	Results for review	0%	0%	1%	0%	1%
	Unacceptable results	0%	0%	0%	0%	0%
Number of cases evaluated Carcinoma		9	20	20	26	22(*)

(*) 2025: At the time of compiling research results, the evaluation results of sample batch 02 were not yet available, so the reported data was based on data up to the end of August 2025.

The research results show that the external quality assessment (EQA) performance of the histopathology laboratories was being maintained at a relatively high level of good evaluation (Figure 5), with the percentage of results requiring technical review or evaluation being approximately 1%. Several technical errors were recorded and commented on directly in the result analysis reports sent to the EQA: tissue fixation technique, slice thickness, staining accuracy of the staining method, or contaminated specimens, etc. Some errors in result evaluation include: incomplete microscopic description, determination of the degree of tumor cell invasion, lack of clinical orientation, etc.). Technical and diagnostic errors were directly recorded by the expert panel in coded result evaluation forms sent with the external quality control slides. Statistics also show the number of cases with recorded carcinomas performed over the years and the percentage of EQA s with correspondingly satisfactory external quality control results. This result was significant in ensuring the role of histopathology in the diagnosis and treatment of malignant diseases.

The current program uses a specific scoring system; however, the conclusions regarding quality standards are currently "good," "needs improvement," and "unacceptable." This needs to be adjusted with more specific evaluation levels to correspond to the statistical evaluation scale, ensuring a more accurate reflection of quality and contributing to the improvement of laboratory quality.

Selection Bias: Participation in the EQA program is voluntary. Therefore, PGPBs with better capabilities and a focus on quality management tend to participate earlier and more regularly. However, the continuous increase in the number of participating pathology laboratories over the years (from 9 to 40) shows that the program is gradually expanding its coverage, minimizing the impact of this bias. pathology laboratories need to actively participate in EQA to gain an objective view of their unit's quality, thereby enabling effective corrective and preventive actions to achieve reliable diagnostic results.

4. CONCLUSION

Quality management of histopathology was not just a technical process but a comprehensive

system requiring close coordination from many different aspects. In Vietnam, significant progress has been made in implementing the external quality control program for histopathology to support histopathology laboratories.

EQA data has demonstrated that the results of quality management in histopathology testing in Vietnam have shown significant improvements during the 2021-2025 period. The participation rate in the program has increased, along with the maintenance of satisfactory evaluation results in external quality control by histopathology laboratories, and the diversification of histopathology techniques suitable for practical implementation at the units. The research results show that the program has contributed to improving quality management at histopathology laboratories nationwide.

5. RECOMMENDATIONS

To further improve quality control results in the field of Pathology, the author proposes the following recommendations:

- When receiving non-conforming external quality control results, the pathology laboratories needs to study recommendations from the external quality control program implementing unit and have a plan for corrective and preventive measures, applying some statistical quality assurance tools suitable to the unit's reality [4].

- The current external quality control program needs to be expanded to include more types of specimens, disease groups and more specialized techniques such as immunohistochemistry and in situ hybridization [5]. This will help meet the increasing needs of pathology laboratories in quality control.

- Develop a more advanced online EQA management system, allowing virtual sample submission, rapid feedback and more in-depth data analysis, while facilitating the continuous collection and analysis of pathology laboratories quality control results.

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