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Original article

Study on the performance of medical laboratories in Romania: microbial etiological agents identification

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Abstract

Medical laboratories must offer reliable services to the patient, and the way to guarantee this is by demonstrating their performance. External Quality Control (EQC) is a tool that helps the laboratories measure their performance, identify possible errors, and improve their activity. The aim of our research has been divided into three segments, which included the evaluation of the accuracy rate in pathogen identification, examining the unsatisfactory results, and investigating the identification methods utilized by the laboratories in Romania. As the analyses of pharyngeal exudate and urine are the most commonly requested in medical laboratories and also in External Quality Control, we have focused on the findings obtained from these programs.

Keywords External Quality Control, pathogen identification, urine cultures, pharyngeal exudate

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Introduction

An essential aspect of the microbiological diagnosis is to provide to physicians rapid and precise outcomes, as they rely on the results of the medical analyses carried out in the medical laboratory in order to confirm 70-85% of the medical diagnoses (C. POPA and G. SORESCU, 2022 [1]) Therefore, in order to achieve this desideratum, a strong connection between the patient, the physician, and the medical laboratory must be built (C. POPA and G. SORESCU, 2022 [1]). Also, medical laboratories must adopt a quality management system to operate with optimal efficiency, for the benefit of patient care (R. B. CAREY & al., 2018 [2]). External Quality Control is an important part of any quality management system. The medical laboratories regularly apply to the EQC programs to achieve continuous improvement of the system. The two main steps of an EQC program are: i) the EQC organizer provides the samples to the medical laboratory in order to be tested and ii) the laboratory examines the samples and then sends the results to the provider.

The key reason for EQC's utility is that the samples are manufactured to simulate the regular patient samples. Furthermore, the participants treat the EQC samples in the same manner as patient samples, using their routine equipment and testing methods (C. POPA and G. SORESCU, 2022 [1]).

Pharyngeal exudate analysis represents an important step to diagnose pharyngitis, which is the most common disease of the upper respiratory tract. Although viruses are the main pathogen responsible, bacteria and fungi also play a significant role in the occurrence of this disease (S. ORZELL and A. SURYADEVARA, 2019 [3]). The most significant bacteria causing upper respiratory tract infections is group A *Streptococcus pyogenes,* followed by group B, C and G streptococci (M. C. CHIFIRIUC & al., 2015 [4]).

Urinary tract infections (UTIs) are a prevalent form of infectious diseases that can occur in individuals of all ages and genders, being considered one of the most common infections worldwide (C. DELCARU & al., 2016, [10]). This kind of infection can be acquired both in the community and in hospitals and have the potential to progress towards severe forms and cause renal failure (A. FLORES-MIRELES & al., 2019 [6]; A. S. N. HAITHAM & al., 2021 [7]; V. C. CRISTEA & al., 2019, [9]). The main pathogens responsible for UTIs are *Escherichia coli* and *Proteus mirabilis* (M. C. CHIFIRIUC et al., 2015 [4]; C. DELCARU & al., 2017 [8]). Regarding immunosuppressed patients, two of the common pathogens are *Candida albicans* and *Candida glabrata* (M. C. CHIFIRIUC & al., 2015 [4]).

The purpose of this study is to evaluate the quality of the services provided by medical laboratories in Romania with respect to the microbial etiological agent identification procedures and performance.

Table 1 – The strains provided in each EQC round organized between 2017 and 2022 for Bacteriology – Urine culture

EQC Round	Strain	Percentage of satisfactory results (%)
March 2017	*Klebsiella pneumoniae*	97.93%
May 2017	*Enterococcus faecalis*	96.76%
September 2017	*Proteus mirabilis*	99.60%
November 2017	*Escherichia coli*	99.60%
March 2018	*Enterococcus faecalis*	99.20%
May 2018	*Proteus mirabilis*	99.26%
September 2018	*Enterobacter cloacae*	85.61%
November 2018	*Pseudomonas aeruginosa*	100.00%
March 2019	*Enterococcus faecalis*	98.58%
May 2019	*Serratia marcescens*	87.16%
September 2019	*Enterobacter cloacae*	91.86%
November 2019	*Escherichia coli*	99.00%
March 2020	*Serratia marcescens*	90.65%
June 2020	*Enterococcus faecalis*	99.31%
September 2020	*Proteus vulgaris*	92.33%
November 2020	Escherichia coli	99.00%
March 2021	*Enterococcus faecalis*	99.32%
May 2021	*Proteus mirabilis*	98.26%
September 2021	*Serratia marcescens*	95.44%
November 2021	*Escherichia coli*	99.70%
March 2022	*Proteus vulgaris*	97.38%
May 2022	*Escherichia coli*	100.00%
September 2022	*Escherichia coli*	99.87%
November 2022	*Escherichia coli*	99.60%

Materials and methods

We have focused our research on urine culture for bacteria and fungi identification and pharyngeal exudate for bacterial identification EQC programs. The results utilized in our study were clustered from the following three EQC schemes, with the participation of 300 to 600 Romanian medical laboratories between 2017 and 2022: Bacteriology – Pharyngeal exudate, Bacteriology – Urine culture and Micology – Urine culture. Therefore, we collected and analyzed the results to gain insight into the performance of Romanian medical laboratories in relation to pathogen identification.

Table 2 – The strains provided in each EQC round organized between 2017 and 2022 for Bacteriology – Pharyngeal exudate

EQC Round	Strain	Percentage of satisfactory resuts (%)
March 2017	*Staphylococcus aureus*	100.00%
May 2017	*Streptococcus agalactiae*	96.30%
September 2017	*Streptococcus pyogenes*	98.76%
November 2017	*Staphylococcus aureus*	100.00%
March 2018	*Streptococcus pyogenes*	99.19%
May 2018	*Streptococcus agalactiae*	96.98%
September 2018	*Streptococcus pyogenes*	99.26%
November 2018	*Staphylococcus aureus MRSA*	100.00%
March 2019	*Streptococcus dysgalactiae subsp. equisimilis*	93.12%
May 2019	*Streptococcus pyogenes*	100.00%
September 2019	Staphylococcus aureus MRSA	99.34%
November 2019	*Streptococcus pyogenes*	100.00%
March 2020	*Streptococcus pyogenes*	99.32%
June 2020	*Streptococcus agalactiae*	95.62%
September 2020	*Staphylococcus aureus MRSA*	100.00%
November 2020	*Streptococcus agalactiae*	98.96%
March 2021	*Streptococcus dysgalactiae subsp. equisimilis*	98.91%
May 2021	*Streptococcus pyogenes*	99.54%
September 2021	*Streptococcus agalactiae*	99.06%
November 2021	*Streptococcus pyogenes*	99.84%
March 2022	*Staphylococcus aureus MRSA*	100.00%
May 2022	*Streptococcus pyogenes*	99.86%
September 2022	*Streptococcus dysgalactiae subsp. equisimilis*	99.07%
November 2022	*Streptococcus agalactiae*	99.59%

Table 3 – The strains provided in each EQC round organized between 2017 and 2022 for Micology – Urine culture

EQC round	Strain	Percentage of satisfactory resuts (%)
March 2017	*Candida albicans*	100.00%
May 2017	*Candida albicans*	98.48%
September 2017	*Candida krusei*	87.31%
November 2017	*Candida albicans*	100.00%
March 2018	*Candida parapsilosis*	95.71%
May 2018	Candida parapsilosis	98.84%
September 2018	*Candida albicans*	99.42%
November 2018	*Candida albicans*	98.90%
March 2019	*Candida albicans*	100.00%
May 2019	*Candida albicans*	98.48%
September 2019	*Candida parapsilosis*	97.52%
November 2019	*Candida parapsilosis*	100.00%
March 2020	*Candida glabrata*	82.56%
June 2020	*Candida parapsilosis*	97.41%
September 2020	*Candida tropicalis*	89.58%
November 2020	*Candida albicans*	99.48%
March 2021	*Candida albicans*	99.50%
May 2021	*Candida glabrata*	97.54%
September 2021	*Candida tropicalis*	93.87%
November 2021	*Candida parapsilosis*	99.56%
March 2022	*Candida albicans*	100.00%
May 2022	*Candida parapsilosis*	99.80%
September 2022	*Candida tropicalis*	97.57%
November 2022	*Candida albicans*	99.38%

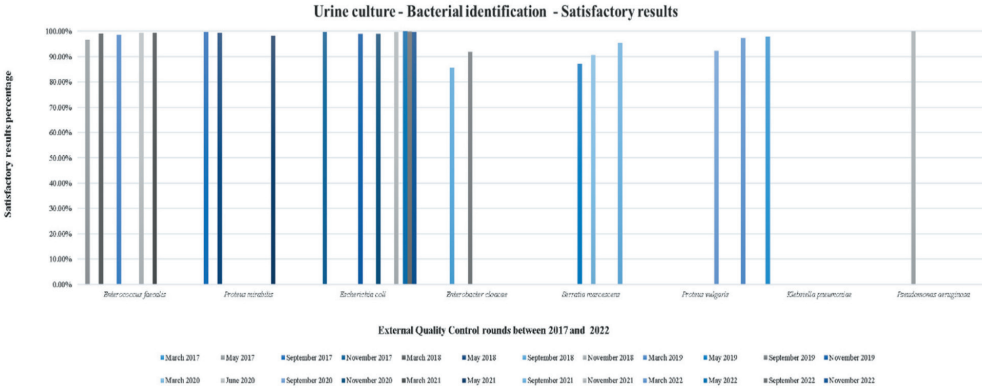

Figure 1 – The centralization of the percentages of satisfactory results obtained from urine culture sample testing

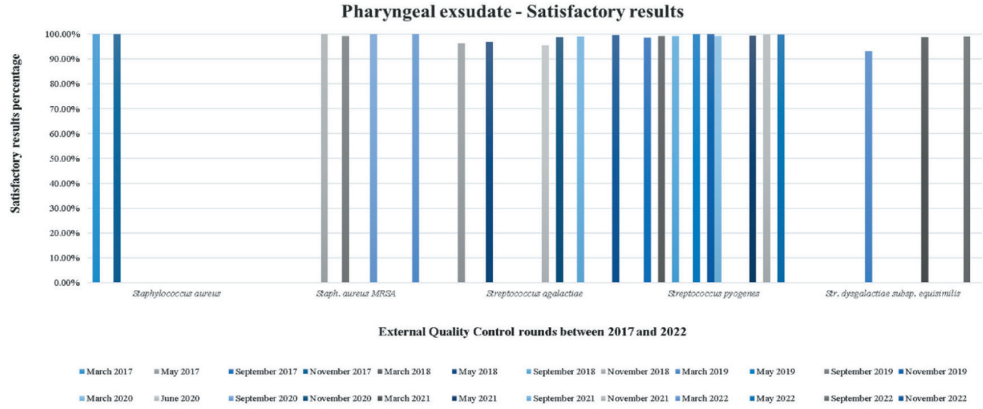

Figure 2 – The centralization of the percentages of satisfactory results obtained from testing pharyngeal exudate samples

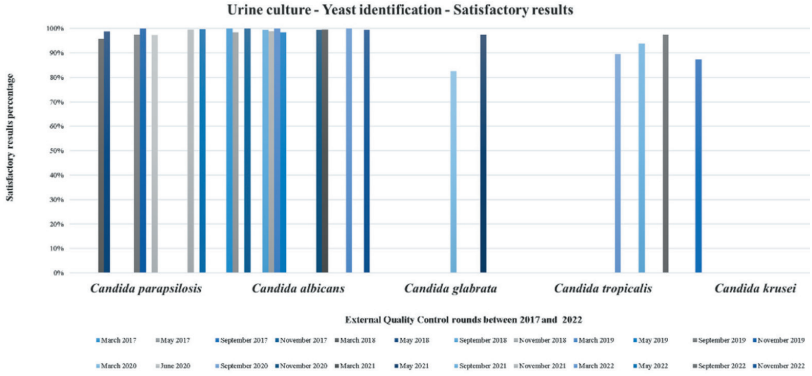

Figure 3 – The centralization of the percentages of satisfactory results obtained from testing urine culture samples – yeast identification

Results

For the analysis of the satisfactory results obtained by testing the strains provided from 2017 to 2022, the study was initiated by gathering the outcomes from the EQC rounds that were conducted from 2017 to 2022. Every round had an approximate number of 300 medical laboratories participating between 2017 and 2020 and an approximate number of 600 medical laboratories participating in 2021 and 2022. Between 2017 and 2022, the External Quality Control organizer supplied different strains for the three EQC schemes (tables no. 1, no. 2, and no. 3).

By centralizing the percentages of satisfactory results registered between 2017 and 2022 (Figure 1), we have observed that *Enterobacter cloacae* and *Serratia marcescens* strains registered the lowest number of satisfactory results. On the other hand, *Pseudomonas aeruginosa, Escherichia coli, Enterococcus faecalis,* and *Proteus mirabilis* registered the highest number of satisfactory results.

The testing of pharyngeal exudate samples revealed that the minimum percentage recorded was 93.12% for *Str. dysgalactiae subsp. equisimilis* strain and the highest (100%) was registered for *S. aureus, S. aureus MRSA,* and *Str. pyogenes* (Figure 2).

The lowest percentage for yeast identification was registered for *C. glabrata* (82.56%), and the highest was 100% for *C. albicans* and *C. parapsilosis*.

Upon analyzing the Urine culture – Yeast identification scheme, it was observed that numerous *Candida sp*. outcomes were frequently obtained, indicating that the laboratories often do not report the species to the patients.

Therefore, we chose to conduct a more detailed analysis on this topic.

Regarding the yeasts identification, the first stage of the analysis revealed that there are more than 150 medical laboratories that usually report "*Candida sp.*" (Table 4).

Going further, we focused on the medical laboratories that reported "*Candida sp.*" results in order to correlate this results with the method used for identification.

The analysis showed that there are three medical laboratories that, in spite of using an automated system for identification, could not identify the *Candida* species provided in the samples (Table 5).

The next step of the study was to analyze the unsatisfactory results registered and the methods used by the laboratories. The total number of unsatisfactory results registered

Table 4 – An overview of the results obtained in urine culture samples from *C. albicans*, *C. parapsilosis*, *C. tropicalis*, and *C. glabrata* strains in 2021 and 2022

EQC Round	Strain	Number of results
May 2021	*Candida glabrata*	*Candida glabrata* = 121
		Candida sp. = 156
September 2021	*Candida tropicalis*	*Candida tropicalis* = 254
		Candida sp. = 175
May 2022	*Candida parapsilosis*	*Candida parapsilosis* = 320
		Candida sp. = 186
November 2022	*Candida albicans*	*Candida albicans* = 329
		Candida sp. = 154

Table 5 – An overview of the results obtained in urine culture samples from *C. albicans*, *C. parapsilosis*, *C. tropicalis*, and *C. glabrata* strains in 2021 and 2022

EQC Round	Strain	Number of *„Candida sp."* results	Number of medical laboratories that use manual method	Number of medical laboratories that use automated system
May 2021	*Candida glabrata*	156	153	3
September 2021	*Candida tropicalis*	175	173	2
May 2022	*Candida parapsilosis*	186	183	3
November 2022	*Candida albicans*	154	154	0

Table 6 – Unsatisfactory results obtained from testing urine culture samples – bacteria identification

Strain	Round and year	No. of unsatisfactory results registered	Total no. of results registered	Unsatisfactory results obtained using manual method for identification	Unsatisfactory results obtained using automated systems for identification
Enterococcus faecalis	May 2017	5	247	5	-
Enterococcus faecalis	March 2018	2	249	2	-
Enterococcus faecalis	March 2019	4	282	4	-
Enterococcus faecalis	June 2020	2	288	2	-
Enterococcus faecalis	March 2021	2	292	2	-
Serratia marcescens	May 2019	38	296	37	1
Serratia marcescens	March 2020	29	310	28	1
Serratia marcescens	September 2021	30	658	30	-
Escherichia coli	November 2017	1	251	1	-
Escherichia coli	November 2019	3	300	3	-
Escherichia coli	November 2020	3	300	3	-
Escherichia coli	November 2021	2	661	2	-
Escherichia coli	September 2022	1	772	1	-
Escherichia coli	November 2022	3	743	3	-
Proteus mirabilis	September 2017	1	247	1	-
Proteus mirabilis	May 2018	2	270	2	-
Proteus mirabilis	May 2021	7	402	7	-
Enterobacter cloacae	September 2018	38	264	38	-
Enterobacter cloacae	September 2019	25	307	25	-
Proteus vulgaris	September 2020	23	300	22	1
Proteus vulgaris	March 2022	15	573	15	-
Klebsiella pneumoniae	March 2017	5	241	5	-

Table 7 – Unsatisfactory results obtained from testing pharyngeal exudate samples

Strain	Round and year	No. of unsatisfactory results registered	Total no. of results registered	Unsatisfactory results obtained using manual method for identification	Unsatisfactory results obtained using automated systems for identification
Staph. aureus MRSA	September 2019	2	302	2	-
Streptococcus agalactiae	May 2017	8	243	8	-
Streptococcus agalactiae	May 2018	8	265	8	-
Streptococcus agalactiae	June 2020	12	274	11	1
Streptococcus agalactiae	November 2020	3	288	3	-
Streptococcus agalactiae	September 2021	6	640	6	-
Streptococcus agalactiae	November 2022	3	729	3	-
Streptococcus pyogenes	September 2017	2	242	2	-
Streptococcus pyogenes	March 2018	2	246	2	-
Streptococcus pyogenes	September 2018	2	269	2	-
Streptococcus pyogenes	March 2020	2	293	2	-
Streptococcus pyogenes	May 2021	2	438	2	-
Streptococcus pyogenes	November 2021	1	635	1	-
Streptococcus pyogenes	May 2022	1	709	1	-
Str. dysgalactiae subsp. equisimilis	March 2019	19	276	19	-
Str. dysgalactiae subsp. equisimilis	March 2021	3	276	3	-
Str. dysgalactiae subsp. equisimilis	September 2022	7	753	7	-

Table 8 – Unsatisfactory results obtained from testing urine samples – yeast identification

Strain	Round and year	No. of unsatisfactory results registered	Total no. of results registered	Unsatisfactory results obtained using manual method for identification	Unsatisfactory results obtained using automated systems for identification
Candida krusei	September 2017	17	134	17	-
Candida albicans	May 2017	2	132	2	-
Candida albicans	September 2018	1	173	1	-
Candida albicans	November 2018	2	181	2	-
Candida albicans	May 2019	3	198	3	-
Candida albicans	November 2020	1	193	1	-
Candida albicans	March 2021	1	200	1	-
Candida albicans	November 2022	3	486	3	-
Candida parapsilosis	March 2018	7	163	7	-
Candida parapsilosis	May 2018	2	173	2	-
Candida parapsilosis	September 2019	5	202	4	1
Candida parapsilosis	June 2020	5	193	5	-
Candida parapsilosis	November 2021	2	451	2	-
Candida parapsilosis	May 2022	1	507	1	-
Candida glabrata	March 2020	34	195	34	-
Candida glabrata	May 2021	7	284	7	-
Candida tropicalis	September 2020	20	192	20	-
Candida tropicalis	September 2021	28	457	26	2
Candida tropicalis	September 2022	13	536	13	-

Table 9 - An overview of the percentage of laboratories that use automated systems between 2017 and 2022 for the EQC scheme Bacteriology – Urine culture

Round and year	Total no of results registered	No. of results obtained using utomated systems	Percentage (%) of results obtained using automated systems
September 2017	247	17	6.88%
September 2018	264	26	9.84%
September 2019	307	40	13.02%
September 2020	300	45	15.00%
September 2021	658	92	13.98%
September 2022	772	97	12.56%

was 241 and only in three cases these were obtained using automated systems (Table 6). Total number of unsatisfactory results registered was 83 and only 1 of them was obtained using automated systems (Table 7).

Total number of unsatisfactory results registered was 154, and only three of them were obtained using automated systems (Table 8).

A total of 478 unsatisfactory results were obtained by centralizing all unsatisfactory results obtained between 2017 and 2022 in the three EQC programs. Only seven of them were obtained using automated systems, the rest of the 471 were obtained using manual methods (Figure 4).

For the analysis of the results provided by the medical laboratories that use automated systems for pathogen identi-

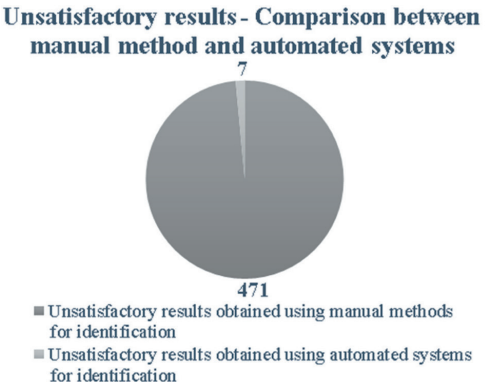

Figure 4 - Comparison between manual method and automated systems

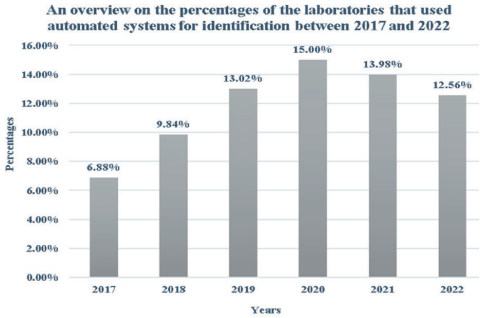

Figure 5 – An overview of the percentage of laboratories that use automated systems between 2017 and 2022

fication, we utilized the outcomes obtained for the urine culture – bacteria identification program, which had the greatest number of participating laboratories and rounds organized in September of each year from 2017 to 2022 (Figure 5).

Two primary concepts are uncovered in this phase of the investigation, i.e.: the percentage of laboratories that use automated systems is significantly low in Romania; moreover, it can be observed that it has not changed considerably during the last 4 years (from 2019 to 2022). However, the percentage has increased compared to 2017.

Conclusions

In Romania, most of the medical laboratories use manual methods when it comes to pathogen identification in patient samples. However, this study shows that in spite of not using automated systems, the laboratories manage to provide reliable services to the patients, as most of the EQC rounds concluded with satisfactory results percentages greater than 90% throughout the 6 years of the study.

Using the data from the EQC provider, we could observe that the participants encountered difficulties in identifying *S. marcescens*, *E. cloacae*, *Str. dysgalactiae subsp. equisimilis*, *P. vulgaris*, *C. glabrata,* and *C. tropicalis*. On the other hand, *S. aureus*, *Str. pyogenes*, *E. coli*, *P. aeruginosa,* and *C. albicans* sample testing registered the highest percentages of satisfactory results.

The study revealed that the percentage of medical laboratories using automated equipments in Romania is very low. It has increased from 2017 to 2020, but unfortunately, it has slightly decreased until 2022.

Most of the unsatisfactory results were obtained using manual methods.

Many laboratories do not usually report the *Candida* species to the patients. This situation brings up the matter of providing the patient with a correct medical prescription.

Acknowledgments

This document complies with the General Data Protection Regulation and the requirements of the international standard applicable to the accreditation of Proficiency Testing Schemes providers regarding the confidentiality of data provided by medical laboratories participating in External Quality Control programs.

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