Original Article
Evaluation of clinical performance of Sciendox 2000R automatic feces analyzer

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Abstract: Objective: To evaluate the clinical performance of Sciendox 2000R automatic excrement analyzer and to validate whether it is suitable for routine clinical examination of excrement. Methods: 424 copies of excrement specimens were collected randomly from the First Affiliated Hospital of Guangzhou University of Traditional Chinese Medicine, and examined by direct microscopic examination and Sciendox 2000R automatic excrement analyzer. We evaluated the performance of Sciendox 2000R analyzer through accuracy test, blank test, repeatability test and contamination rate test as well as fetal occult blood (FOB) test. Results: The detection rate of red blood cells (RBC), white blood cells (WBC) and parasite ovum by Sciendox 2000R analyzer was 2.12% (9/424), 4.48% (19/424) and 7.31% (31/424) respectively, and detection rate of FOB was 19.81%; Compared with direct smear microscopy method, there was no statistical significance in differences. The background, repeatability and contamination rate of the instrument was good. Conclusions: The results of Sciendox 2000R analyzer were comparable to the results of direct microscopic examination. In addition, the equipment had low background, good repeatability, low contamination rate and good biological safety. The functions could basically satisfy the requirements of clinical excrement analysis.

Keywords: Automatic excrement analyzer, direct microscopic examination, performance

Introduction

Excrement routine examination has great significance for the diagnosis of intestinal infectious diseases, gastrointestinal diseases and parasitic diseases [1, 2], and is a routine examination for intestinal outpatients and inpatients [3, 4]. At present, the excrement examination mainly uses traditional smear macroscopic observation with naked eyes, which has been used for decades, belonging to the pure manual operation; it could be greatly influenced by subjective factors that make the examination difficult to achieve standardization or control the testing quality [5]. In recent years, in order to overcome the disadvantages of manual operation, many companies have developed fully automatic excrement analyzer to solve the above problems [6]. However, all kinds of instruments need to be evaluated in order to ensure the quality of test before being applied in clinic [7]. This study aimed at evaluating the performance of 2000R Sciendox automatic excrement analyzer in order to evaluate its clinical application value.

Materials and methods

Specimen source

Excrement samples from 424 cases of patients were randomly collected at the First Affiliated Hospital of Guangzhou University of Chinese Medicine from March 2015 to September.

Instruments and reagents

Olympus CH20 microscope (Olympus); Sciendox 2000R automatic excrement analyzer, sampling tubes and filtering tubes (Xiamen channel Biotechnology Co., Ltd.); 0.9% sodium chloride solution and 500 mg/L sodium hypochlorite solution (Tianjin Fu Yu Fine Chemical Co., Ltd.); Feces occult blood detection kit (colloidal gold) (Xiamen boson Biotechnology Co., Ltd.) [8]; Feces occult blood (FOB) detection kit (colloidal

Table 1. Comparison of detection rate on same sample between two methods

Items	Manual method		Instrument method		χ^2	P
	Detected cases	Detection rate	Detected cases	Detection rate		
RBC	11	2.59%	9	2.12%	0.5	0.5
WBC	22	5.19%	19	4.48%	1.33	0.25
Parasite ovums	36	8.49%	31	7.31%	3.2	0.063
Total	69	16.27%	59	13.91%		

gold) (Hangzhou ABON biological medicine Co., Ltd.).

Evaluation of the accuracy of instrument inspection

Direct smear for microscopic examination (manual method): experienced technicians operated in strict accordance with the *National Clinical Laboratory Operation Rules* (3rd Edition) [9] on the requirements on direct smear for microscopic examination, all specimens examination finished in 2 hours after collection.

Sciendox 2000R automatic excrement analyzer (instrument method): all specimens were analyzed immediately after manual examination in accordance with the instruction of the instrument manual. With the manual method as the reference, the results of both methods were compared, to detect the accuracy of the instrument method.

Blank test

The blank sample collector was directly analyzed by instrument method for 3 times, and the results were regarded as the blank control result.

Repeatability evaluation of instrument method

Specimens containing RBC and/or WBC (++ or beyond), RBC and/or WBC (+) were repeatedly measured 10 times by instrument method to observe the repeatability of instrument method.

Evaluation of contamination rate of instrument method

Specimens with RBC and/or WBC (++ or beyond) and positive FOB were selected as positive samples, while the samples with nega-

tive results were selected as negative specimens; the negative samples were consecutively tested for 3 times by instrument method following 3 times examination of positive specimens to evaluate the contamination rate [10, 11].

Fecal occult blood test

All excrement specimens were treated with both manual method and instrument method for occult blood test [12, 13] the two methods were in strict accordance with the reagent instructions.

Experiment on improving the detection rate of parasite ovum of instrument method

Instrument method was adopted to detect two samples with positive clonorchis sinensis ovum [14]. Set the number of photo shots of the instrument to 10, and examine the samples for 10 consecutive times; and then set the number of photo shots to 20, 30 and 60 respectively and examine the samples for 10 times of each, to find out the most suitable shots for increasing the detection rate of parasite ovum.

Statistics analysis

SPSS 18.0 software was used for data collection and statistical analysis. Paired data χ^2 test was used to analyze the data, and *P* < 0.05 was considered statistically significant.

Results

The accuracy of the instrument method

For the randomly selected 424 excrement specimens, the detection rates of instrument method on red blood cells, white blood cells and parasite ovum were 2.12% (9/424), 4.48% (19/424) and 7.31% (31/424), respectively, which were slightly lower than the detection rates of manual method without statistical significance (*P* > 0.05). The false negative rate and false positive rate of instrument method on detecting red blood cells, white blood cells and parasite ovum were (18.18%, 0), (13.64%, 0), and (13.89%, 0), respectively. These results showed that the detection results of 2000R Sciendox automatic excrement analyzer were

Table 2. Results of Instrument Method for red blood cells and white blood cells

Times	RBC			WBC		
	Specimen1	Specimen2	Specimen3	Specimen4	Specimen5	Specimen6
1	-	+	+++	-	+	+++
2	-	+	+++	-	+	+++
3	-	+	+++	-	+	+++
4	-	+	+++	-	+	+++
5	-	+	+++	-	+	+++
6	-	+	+++	-	+	+++
7	-	+	+++	-	+	+++
8	-	+	+++	-	+	+++
9	-	+	+++	-	+	+++
10	-	+	+++	-	+	+++
Coincidence rate	100%	100%	100%	100%	100%	100%

Table 3. Experiment of Contamination Rate

Items	H1	H2	H3	L1	L2	L3
RBC	+++	+++	+++	0	0	0
WBC	++	++	++	0	0	0
FOB	+	+	+	-	-	-

Table 4. Results of FOB Test by both methods (case)

Manual Methods	Instrument method		Total
	Positive	Negative	
Positive	77	5	82
Negative	7	335	342
Total	84	340	424

Note: P=0.774, χ^2=0.75.

highly consistent with the manual method, and the accuracy of the instrument was better. See **Table 1**.

Results of the blank test by instrument method

Blank sample was tested for three times, and the results showed that red blood cells, white blood cells and parasite ovum as well as feces occult blood were all negative for each time, indicating the low detect background of the instrument.

Repeatability of instrument method

Samples with RBC (-) (+) (+++) and WBC (-) (+) (+++) by manual method were select, one sample for each type. Then, the chosen samples were examined by instrument method for 10 consecutive times, and each detection showed

(-) (+) (+++), indicating good repeatability of instrument method. See **Table 2**.

Contamination rate of instrument method

The contamination rates of instrument detection on red and white blood cells and the occult blood were all zero. See **Table 3**.

Results of FOB test

The detection rate, false negative rate and false positive rate on feces occult blood test by colloidal gold kits used on Sciendox 2000R automatic excrement analyzer were 19.81%, 6.10% and 8.54%, respectively, while the detection rate of manual method was 19.34%. There was no significant difference between the two methods. The results suggested that the two methods were comparable on the detection results of feces occult blood test. See **Table 4**.

The number of photo shots and the detection rate of parasite ovum

With the increasing in number of photo shots, the detection rate of parasite ovum was improved, which is in favor of reducing the missing rate. See **Table 5**.

Discussion

Automatic detection, with its advantages in automation, high efficiency, easy standardization and manpower saving etc. has become the trend of the development of laboratory detection at home and abroad [15]. With the continu-

Table 5. Correlation between Number of Pictures and the Detection Rate of Parasite Ovums

Numbers of Pictures	Detection Rate of Parasite Ovums (%)
10	65
20	75
30	90
60	95

ous progress in science and technology, most of the inspections in laboratory have gradually realized automation [16]. However, the examinations of excrement, such as fecal excretion and secretion, are still stuck in the traditional manual methods; the automatic examination instruments haven't been systematically and thoroughly introduced to clinical application [17]. Because of the particularity of the examination of excrement specimens, most of those are still tested by primitive manual smear [18]. In fact, the automatic detection instruments for excrement examination have emerged. The detection principles are divided into two types: handwork imitation fecal analysis workstation and filter suspended fecal analysis workstation [19]. The Sciendox type 2000R automatic analyzer used in this study adopts suspension filtration principle, and uses specialized excrement collection tube and Sciendox full filtration sample processing technology, so that the process of specimen can be carried out in a safe and relatively closed and fully automatic condition, to ensure the examination quality. In the aspect of morphological detection, the fully automatic microscopy technologies, such as automatic focusing and automatic acquisition of images etc. ensure the accuracy and reliability of test results. The instrument can also specifically target the specimen according to preset photo shots of high/low power lens to greatly improve the efficiency. The four-channel design greatly improves the detection speed. Centralized treatment of waste gas/liquid and disposable supplies greatly improves biological safety and reduces the contamination on experimental environment and technicians. How is the performance of automatic instrument in the clinical application? There is no profound performance evaluation at present.

In this experiment, we conducted a comparison between direct smear microscopic examination and instrument examination. The detection rates on red blood cells, white blood cell and parasite ovum by instrument method were slightly lower than that of manual method, but the difference was not statistically significant, indicating the two methods are in good agreement. Attention needs to be paid on the detection rate on parasite ovums, the *P* value of instrument method was 0.063, which was close to the critical value (*P*=0.05), indicating the detection rate on parasite ovum by instrument method was lower than that of manual method and need to be further improved. In fact, to improve the detection rate of the parasite ovums, we increased the photo shots of two false negative samples of parasite ovum from the original 10 shots to 20, 30 and 60 shots. The detection rate was improved significantly, however, the results from 30 shots and 60 shots were not significant different. Moreover, 60 shots for each sample will occupy large stock memory, and significantly reduce the detection speed. Therefore, appropriate increase of the photo shots could be used as an attempt to improve the detection rate of parasite ovums.

This experiment also carried out blank test, repeatability test and contamination rate valuation on the automatic excrement analyzer. The results showed that the instrument has advantages of low background, good repeatability and low contamination rate. In addition, the instrument can also detect the fat globulins [20], fungi and spores in the specimen; however, due to the small number of the positive samples, those results were not included in the statistical data.

To sum up, Sciendox 2000R automatic excrement analyzer, as a sophisticated fecal analysis workstation, its high accuracy, low background, good repeatability, and low contamination rate as well as good biological safety, simple operation and rapid detection can satisfy the requirements of clinical routine excrement examination. However, in actual practice, we still need to work out a set of experience, to optimize the examination results under different characters and different volume of specimens and to control the best proportion of the amount of diluted liquid, to achieve total quality control and standardization, which needs to be explored in the future clinical practice.

Disclosure of conflict of interest

None.

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