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ORIGINAL ARTICLE

Clinical Performance Evaluation of Feces Analyzer KU-F10

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SUMMARY

Background: **Systematic performance verification is required before a laboratory can introduce a new measurement procedure for reporting results of patient testing. The aim of this study was to explore the basic performance and clinical application value of KU-F10 Feces analyzer.**
Methods: **We collected 530 fecal specimens in our hospital from October 2019 to February 2020, using manual methods as the gold standard. Then we made a comprehensive evaluation from repeatability, carried pollution rate, coincidence rate of formed element, and coincidence rate of fecal occult blood test.**
Results: **The sensitivity of white blood cells was 90.3%, the specificity was 99.2%, and the coincidence rate with microscopy was 98.7%; the sensitivity of the instrument to detect red blood cells was 90.3%, the specificity was 98.2%, and the coincidence rate with microscopy was 97.7%, The sensitivity of the instrument to detect fungi is 100.0%, the specificity is 98.7%, and the coincidence rate with the microscopy is 98.7%. The sensitivity of the instrument to detect fat globules is 94.7%, the specificity is 99.0%, the coincidence rate with the microscopy is 98.9%. Comparison of instrumental fecal occult blood test and reagent B fecal occult blood result: On the 387 cases tested fecal samples, the sensitivity of the instrument was 83.8%, the specificity was 96.5%, and the coincidence rate with the results of microscopy was 92.3%. FOB minimum detection limit is 0.1 μg/mL and detection range is 0.1 to 2,000 μg/mL.**
Conclusions: **The KU-F10 feces analyzer has an advantage of a high degree of automation, simple operation procedures, fast detection speed, improved working environment, improved work efficiency, and higher clinical application value.**
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KEY WORDS

fecal occult blood test, feces analyzer, manual method, coincidence rate

INTRODUCTION

Feces is the final product of food in the human digestive tract. Therefore, through feces routine examination, you can know whether the digestive tract is infected or bleeding. The fecal occult blood test (FOBT) has important clinical significance, can be used for the diagnosis of gastrointestinal bleeding [1], the identification of gastrointestinal ulcers and tumor bleeding [2], and is helpful for the early diagnosis of gastrointestinal tumors [3, 4]. Fecal detection includes general physical examination [2], chemical examination [5], and formed element analysis [6]. In addition, the application of molecular

markers detection in feces has also been developed [7, 8].

Routine fecal detection usually uses the microscopic detection method, which is time-consuming, labor-intensive and nasty smells makes medical staff heavy burden. In order to improve the situation and work efficiency, we verified performance of the KU-F10 feces analyzer, initially discussed its basic performance and clinical application performance to ensure that the instrument can be used clinically.

MATERIALS AND METHODS

Sample Origin

A total of 530 outpatient and inpatient specimens were collected from October 2019 to February 2020, including 300 males and 230 females, aged 1 day to 98 years with an average age of 57.1 years.

Instruments and reagents

KU-F10 Feces analyzer (Zhuhai Keyu Biological Engineering Co., Ltd.), OLYMPUS microscope (Olympus Japan); supporting fecal occult blood FOB test cassette, cleaning solution, sample diluent, and fecal occult blood quality control products (Zhuhai Keyu Biological Engineering Co., Ltd), Artificial BASO fecal occult blood reagent (double method) (abbreviated as B reagent) (Zhuhai Besso Biotechnology Co., Ltd.), 0.9% saline.

Feces Analysis

Collect outpatient and inpatient samples every day and process fecal routine by microscope and instrument method. The fecal occult blood test was tested by manual B reagent and instrument method.

Basic performance of the instrument

Carry pollution rate: prepare a simulated sample with concentration of 500/μL red blood cells and saline solution. First, the simulated sample with concentration of 500/μL red blood cells was tested three times in succession, test results are H1, H2, H3. The saline was tested three times in succession, and the test results were L1, L2, L3. The calculated carry pollution rate = (L1 - L3)/(H3 - L3) * 100%. The calculated carry pollution rate of the analyzer is ≤ 0.05%.

Repeatability of formed element: prepare simulated samples with concentration of 50/μL and 250/μL red blood cells and test the samples 20 times each. Calculate the coefficient of variation CV% from the obtained data. When the red blood cell concentration is 50 ~ 200/μL, CV ≤ 20%; when the red blood cell concentration is > 200/μL, CV ≤ 15%.

Repeatability of fecal occult blood: Take one negative and positive specimen, and divide them into 20 equal parts respectively, perform 40 tests on these 40 samples. The results after automatic computer identification are used to judge the repeatability. Positive samples shall not show negative results, and negative samples shall not show positive results; the coincidence rate of repeated test results is not less than 100%.

Clinical application indicators

Comparison of formed element: Detect formed element in 530 feces samples by microscopy and instrument methods. Using microscopy as the gold standard (in accordance with the requirements of the fourth edition of the "National Clinical Inspection Operating Procedures" for testing), calculate the coincidence rate of WBC, RBC, fungi, fat globules with manual microscopy results.

FOB comparison: Detect fecal occult blood test in 387 feces samples by manual B reagent and instrument method. Take Reagent B as the gold standard (in accordance with the requirements of the BASO double method fecal occult blood reagent instructions) to calculate the coincidence rate of fecal occult blood and manual B reagent results.

FOB minimum detection limit and detection range: configure Hb suspensions with concentrations of 0.05 μg/mL, 0.1 μg/mL, 500 μg/mL, 2,000 μg/mL, and 3,000 μg/mL, detect separately by the instrument method and B reagent.

Statistical methods

SPSS 16.0 statistical software was used to analyze the data. The count data was expressed as the number of cases (%). The consistency was determined by the kappa test, the comparison between groups was by the χ^2 test, and $p < 0.05$ was considered statistically significant.

RESULTS

Basic performance of the instrument

Carry pollution rate: prepare a simulated sample with concentration of 500/μL red blood cells and saline solution. First, the simulated sample with a concentration of 500/μL red blood cells was tested three times in succession, test results are H1, H2, H3. The saline was tested three times in succession, and the test results were L1, L2, L3. The calculated carry pollution rate = (L1 - L3)/(H3 - L3) * 100% = 0%, indicating the instrumental method avoids carry pollution. No cross-contamination occurred (Table 1).

Repeatability test: Repeatability of formed element: Simulated specimens with concentrations of 50/μL and 250/μL red blood cell, respectively tested 20 times for each concentration, and the CV was 6.4% and 10.0%, which all met the judgment standard. Instrumental test of formed elements had good repeatability (Table 2).

Repeatability of fecal occult blood test: 20 equal parts of positive specimens were tested 20 times, no negative results showed. Then, 20 equal parts of negative specimens were tested 20 times, no negative results showed. The coincidence rate was 100%, which met the judgment standard, and the instrument fecal occult blood

Table 1. Carry pollution rate.

Sample No.	1	2	3	4	5	6
RBC count (/μL)	490	510	495	0	0	0
Carry pollution rate	0%					

Table 2. Repeatability of formed element.

Sample No.	1	2	3	4	5	6	7	8	9	10
RBC count (/μL)	236	206	226	222	214	226	218	232	262	236
Sample No.	11	12	13	14	15	16	17	18	19	20
RBC count (/μL)	244	228	245	258	239	243	252	253	236	253
CV (%)	6.4%									
Sample No.	1	2	3	4	5	6	7	8	9	10
RBC count (/μL)	55	47	53	51	43	40	42	53	51	48
Sample No.	11	12	13	14	15	16	17	18	19	20
RBC count (/μL)	49	42	50	53	55	47	42	44	46	48
CV (%)	10.0%									

Table 3. KU-F10 and microscopy detection for WBC in fecal samples (cases).

KU-F10	Microscopy		Total
	positive	negative	
Positive	28	4	32
Negative	3	495	498
Total	31	499	530

Table 4. KU-F10 and microscopy detection for RBC in fecal samples (cases).

KU-F10	Microscopy		Total
	positive	negative	
Positive	28	9	37
Negative	3	490	493
Total	31	499	530

Table 5. KU-F10 and microscopy detection for fungi in fecal samples (cases).

KU-F10	Microscopy		Total
	positive	negative	
Positive	7	7	14
Negative	0	516	516
Total	7	523	530

Table 6. KU-F10 and microscopy detection for fat globules in fecal samples (cases).

KU-F10	Microscopy		Total
	positive	negative	
Positive	18	5	23
Negative	1	506	507
Total	19	511	530

Table 7. Performance evaluation of KU-F10 and microscopy fecal detection.

Items	Positive rate		Sensitivity	Specificity	Coincidence rate	kappa	p
	Microscopy	KU-F10					
WBC	5.85	6.04	90.3	99.2	98.5	0.882	0.897
RBC	5.85	6.98	90.3	98.2	97.7	0.812	0.452
Fungi	2.64	2.64	100	98.7	98.7	0.839	0.123
Fat globule	3.59	4.34	94.7	99.0	98.7	0.882	0.524

Table 8. KU-F10 and microscopy detection for FOB in fecal samples (cases).

KU-F10	Microscope			Total
	positive	weak-positive	negative	
Positive	93	2	0	95
Weak positive	12	40	8	60
Negative	6	2	224	232
Total	111	44	232	387

Table 9. Minimum detection limit and detection range of KU-F10 and B reagents.

Hb (μg/mL)	Manual	Microscope instrumental
0.05	-	-
0.1	±	±
500	+	+
2,000	±	±
3,000	-	-

test had good repeatability.

Clinical application indicators

Comparison of instrumental and manual microscopy detection: on the 530 tested fecal samples, the results of instrumental and manual microscopy are shown in Table 3 - 7. The sensitivity of white blood cells was 90.3%, the specificity was 99.2%, and the coincidence rate with microscopy was 98.7%; the sensitivity of the instrument to detect red blood cells was 90.3%, the specificity was 98.2%, and the coincidence rate with microscopy was 97.7%. The sensitivity of the instrument to detect fungi is 100.0%, the specificity is 98.7%, and the coincidence rate with the microscopy is 98.7%.

The sensitivity of the instrument to detect fat globules is 94.7%, the specificity is 99.0%, the coincidence rate with the microscopy is 98.9%.

Comparison of instrumental fecal occult blood test and reagent B fecal occult blood result: Of the 387 tested fecal samples, the sensitivity of the instrumental was 83.8%, the specificity was 96.5%, and the coincidence rate with the results of microscopy was 92.3% (Table 8), kappa value is 0.860, p = 1.00.

FOB minimum detection limit and detection range

The instrumental method and reagent B are used to detect the Hb suspension, the results show that the minimum detection limit of the instrumental method is 0.1 μg/mL and the detection range is 0.1 to 2,000 μg/mL. The results of manual method and instrument method are consistent (Table 9).

DISCUSSION

In the daily specimen test, each fecal routine and fecal occult blood test must be manually smeared and microscopically detected, diluted manually. In addition, there is significant odor, it is labor intensive and time-consuming with many interference factors, has a high biological safety risk coefficient, and many other problems which cause a series of uncertainties. With the rapid development of automated instruments, fecal detection has gradually transitioned from manual methods to automatic analyzer methods. The automatic analyzer method is easy and fast to operate, has low interference factors, low risk factor, and intelligent throughout the process [9]. These advantages can effectively reduce the labor intensity of the medical staff and greatly improve the work efficiency and laboratory safety.

The KU-F10 feces analyzer introduced by our hospital is produced by Zhuhai Keyu Biological Engineering Co., Ltd. The instrument adapts the principle of fecal microscope image analysis including automatic sample dilution, mixing, and spotting. After the sedimentation, the camera will take photos of the formed elements in the feces and automatic interpretation using a colloidal gold detection card. Sample characteristics, formed element images, and fecal occult blood images are on the same interface, and then the results are transmitted after being reviewed by manual method. In order to ensure that the instrument can be used clinically, the manual method was used as the gold standard, and it was comprehensively evaluated in terms of repeatability, carry pollution rate, coincidence rate of formed element, and fecal occult blood tests.

From the basic performance, the KU-F10 carrying pollution rate, the repeatability rate of formed element, and fecal occult blood test are all within the allowable range. The basic performance is in accordance with the manufacturer's statement. In order to ensure accurate sample quantification, the specially designed specimen collection cup can effectively filter fecal residues to prevent blocking, and the maximum detection speed of KU-F10 is not less than 70 tests/hour, which can meet clinical needs.

From the perspective of clinical application performance, the sensitivity of KU-F10 to detect WBC, RBC, fungi, and fat globules in routine examination of 530 cases was 90.3%, 90.3%, 100%, 94.7%, and the specificity was 99.2%, 98.2%, 98.7%, 99.0%, the coincidence rates are 98.7%, 97.7%, 98.7%, 98.9%, and the kappa values are 0.882, 0.812, 0.839, and 0.882. From the above results, it can be seen that the KU-F10 test and microscopy both have good consistency ($p > 0.05$), which is basically consistent with the reports of other types of stool analyzers.

The fecal occult blood test uses a colloidal gold method test card. The colloidal gold has the advantage of stable properties, high sensitivity, good specificity, and is not affected by food, iron, and vitamin C. There is no need for fasting [10,11].

Among the 387 fecal samples, 30 fecal samples did not match the test results. Among them, 12 cases of B reagent detected positive and KU-F10 detected weak positives. The main reason is the excess of antigen (hook effect) caused by massive gastrointestinal bleeding, which is also the main reason for the sensitivity of fecal occult blood only 83.8%; 2 cases B reagent detected weak positive, KU-F10 detects positives; 8 cases B reagent detect negative, KU-F10 detects weak positives; 6 cases B reagent detect positive, KU-F10 detects negative; 2 cases B reagent detect weak positive, KU-F10 detects negative, which may be the subjectivity of the operator's judgment on weak positive, caused by a different position of the colloidal gold test card coating. If the sample is in a different picked position and amount or less amount of the specimen, the large dilution factor is relatively large, etc.

Therefore, the KU-F10 fecal occult blood test is easy to standardize, convenient for detection, and has accurate interpretation. The matching multi-level indefinite quality control products can ensure the accuracy of the test results.

CONCLUSION

In summary, we found that the KU-F10 Feces analyzer has a high degree of automation, and simple operation procedures from sampling, dilution, mixing, spotting, image collection, and cleaning can all be automatically completed by the instrument, which is easy to standardize. It accelerates the detection speed, improves the working environment and the work efficiency and has high level of clinical application value.

Declaration of Interest:

The authors report no competing financial interests.

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