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Automatic sample processing system for medical use

医用全自动样本处理系统

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Foreword

SAC/TC 136 is in charge of this English translation. In case of any doubt about the contents of English translation, the Chinese original shall be considered authoritative.

This document is drafted in accordance with the rules given in GB/T 1.1—2020 Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents.

Attention is drawn to the possibility that some of the contents of this standard may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights.

This document was proposed by National Medical Products Administration.

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Automatic sample processing system for medical use

1 Scope

This document specifies the requirements, identification, labels and instructions for use, packaging, storage, and transportation of the medical automatic sample processing system, and describes the corresponding test methods.

This document is applicable to the pre- and post-analytical clinical sample processing system based on automated track and information network technology, and is not applicable to the equipment with pre-analysis reagent and sample precision filling function of clinical test analysis instrument.

2 Normative references

The contents of the following normative documents contain provisions which, through reference in this text, constitute essential provisions of this document. For dated references, only the edition cited applies to this document; for undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 191 *Packaging—Pictorial marking for handling of goods*

GB/T 14710 *Environmental requirement and test methods for medical electrical equipment*

GB/T 18268.1 *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements*

GB/T 29791.3 *In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use*

GB/T 42125.1 *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements*

GB/T 42125.5 *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 5: Particular requirements for laboratory centrifuges*

GB/T 42125.14 *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 14: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*

YY/T 0086-2020 *Medical refrigerator*

YY/T 0657-2017 *Medical centrifuge*

3 Terms and definitions

No terms and definitions listed in this document.

4 General requirement

Automatic sample processing system for medical use refers to an integrated testing system, which connecting medical analysis module using automatic track and information network technology. Medical automatic sample processing system is usually composed of Sample entry module, centrifuge module, decapper module, sample tube division cup module, track module, interface module, recapper module, sample output module, sample storage module, software module, etc., not including sample reaction, signal acquisition and analysis module. Manufacturer can freely use the module in combination according to the requirements. This document only involves the sample processing module of the integrated testing system, refer to the relevant product standards for testing functionality module. For modules or products not listed in this document, manufacturer shall specify accordingly according to the product characteristics and use needs.

5 Requirements

5.1 Sample entry module

5.1.1 Capacity

The capacity of sample entry module shall not be less than the capacity claimed by the manufacturer.

5.1.2 Default area capacity

The capacity of default area shall not be less than the capacity claimed by the manufacturer.

5.1.3 Barcode identification accuracy

Identification accuracy shall not be less than 99.99%.

5.1.4 Sample tube cover identification

Sample entry module shall have the function of identifying whether tube has cover or/not before loading, and the accuracy of identification shall not be less than 99.99%.

5.1.5 Barcode identification

Sample entry module shall support the following coding formats as a minimum: Code128, Code39 and Codabar barcode.

5.1.6 Prompt message

A prompt message shall be sent when the sample entry module has any of the following situations:

- a) the default area reaches the capacity limit.
- b) the sample tube fails to be transferred or the manipulator fails to grab the sample tube.
- c) the sample tube under the following conditions:
 - 1) barcode ID (ID number) is not readable;
 - 2) duplicate barcode ID;
 - 3) no test order has been set.

5.2 Centrifuge module

5.2.1 The centrifuge throughput

It shall not be less than the throughput claimed by the manufacturer.

5.2.2 Relative deviation of rotational speed

The relative deviation shall be within the range of $\pm 2.5\%$ at the rated voltage and the maximum load corresponding to the maximum rotational speed.

5.2.3 Rotational speed stability accuracy

The rotational speed stability accuracy shall be within the range of $\pm 1\%$ at the rated voltage and the maximum load corresponding to the maximum rotational speed.

5.2.4 Capacity

The capacity shall not be less than the capacity claimed by the manufacturer.

5.2.5 Noise

The noise shall not exceed 70 dB (A) at the maximum load corresponding to the maximum rotational speed.

5.2.6 Amplitude

The amplitude shall not exceed 0.1 mm and the operation shall be stable at the maximum load corresponding to the maximum rotational speed.

5.2.7 Temperature rise

The temperature increase of the test liquid in the non-refrigerated centrifuge tube shall meet the requirements in Table 1.

Table 1 Test liquid temperature rise

Name	Running time/min	The temperature of the test liquid was raised/°C
High speed centrifuge	15	≤ 12
Low speed centrifuge	20	≤ 10
Low speed large capacity centrifuge	20	≤ 10

5.2.8 Timing device

The relative deviation of the digital timing device shall be within $\pm 1\%$.

5.2.9 Time for speed raising and reduction

The time for speed raising and reduction of centrifuge shall meet the requirements in Table 2.

Table 2 Speed raising and reduction of centrifuge

Name	Speed-up time / min	Speed reduction time / min
High speed refrigerated centrifuge	≤ 5	≤ 7
High speed centrifuge	≤ 5	≤ 7
Low speed refrigerated centrifuge	≤ 3	≤ 5
Low speed centrifuge	≤ 5	≤ 7
Low speed large capacity centrifuge	≤ 6	≤ 8
Low-speed refrigerated and large-capacity centrifuge	≤ 6	≤ 8

5.2.10 Main function

The main function of centrifuge module shall meet the following requirements:

- customize the centrifugal speed, temperature and time parameters within the range specified by the manufacturer;
- automatic balancing before centrifugation.

5.2.11 Prompt message

A prompt message shall be sent when the centrifuge module has any of the following situations:

- a) temperature of the centrifugal chamber is abnormal;
- b) balancing fails before centrifugation;
- c) abnormal vibration is detected during centrifugation.

5.3 Decapper module

5.3.1 Throughput

It shall not be less than the throughput claimed by the manufacturer.

5.3.2 Decapping success rate

The success rate shall not be less than 99.99%.

5.3.3 Waste box capacity

It shall not be less than the capacity claimed by the manufacturer.

5.3.4 Main function

The main function of decapper module shall meet the following requirements:

- a) biosafety protection when tube cap is removed;
- b) be able to detect cap presence before and after capping.

5.3.5 Prompt message

A prompt message shall be sent when the decapper module has any of the following situations:

- a) decapping fails;
- b) waste box reaches the capacity limit.

5.4 Sample tube division cup module

5.4.1 Throughput

The throughput shall not be less than that claimed by the manufacturer.

5.4.2 Volume accuracy and reproducibility of the division cup

The accuracy deviation shall be within $\pm 10\%$ with a coefficient of variation (CV) $\leq 5\%$.

5.4.3 Main function

The main function of sample tube division cup module shall meet the following requirements:

- a) automatic label printing;
- b) automatic labeling;

- c) air suction and clot detection of the division pipette;
- d) liquid level detection;
- e) consumables insufficient quantity warning, such as disposable pipette tip (tip) and label.

5.4.4 Prompt message

A prompt message shall be sent when the sample tube division cup module has any of the following situations:

- a) dividing fails;
- b) container with the discarded tip reaches the capacity limit.

5.5 Track module

5.5.1 Sample transportation

The transportation shall be overall stable and reliable, no obvious stuck.

5.5.2 Track Throughput

It shall not be lower than the speed claimed by the manufacturer.

5.5.3 Amplitude

The amplitude shall not exceed 0.1 mm and the track operation shall be stable at the maximum running speed.

5.5.4 Prompt message

A prompt message shall be sent when the movement of the sample carrier is blocked or collided in the track.

5.6 Interface module

5.6.1 Main function

The main function of interface module shall meet the following requirements:

- a) the connectivity of analytical equipment, such as immunoassay, biochemical and coagulation devices claimed by the manufacturer, shall be supported;
- b) third-party device connection should be supported.

5.6.2 Prompt message

A prompt message shall be sent when the sample carrier movement is blocked or

collided.

5.7 Recapper module

5.7.1 Throughput

It shall not be less than the throughput claimed by the manufacturer.

5.7.2 Recapper success rate

The success rate shall not be less than 99.99%.

5.7.3 Main function

The main function of recapper module shall meet the following requirements:

- a) be able to identify the capping or sealing state automatically when the sample tube arrives;
- b) batch capping or film sealing.

5.7.4 Prompt message

A prompt message shall be sent when the recapper module has any of the following situations:

- a) the consumables of caps or films are insufficient;
- b) the capping or sealing fails.

5.8 Sample output module

5.8.1 Capacity

It shall not be less than the capacity claimed by the manufacturer.

5.8.2 Main function

The main function of sample output module shall meet the following requirements:

- a) sample sorting and storage;
- b) automatic sample archiving, and archiving information uploading.

5.8.3 Prompt message

A prompt message shall be sent when the sample output module has any of the following situations:

- a) the sample rack is fully loaded;
- b) the sample tube fails to be transferred or the robot fails to grab the sample tube.

5.9 Sample storage module

5.9.1 Storage temperature

The temperature is set to 5°C, in a steady state, meeting the following requirements:

- a) The temperature of each measuring point shall be within the range of 2°C ~ 8°C;
- b) The chamber temperature shall be within the range of 3.5°C ~ 6.5°C;
- c) The instantaneous value of the temperature of each measuring point in the cabin shall not be less than 0.5°C.

5.9.2 Capacity

It shall not be less than the capacity claimed by the manufacturer.

5.9.3 Waste box capacity

The capacity of waste box shall not be less than the capacity claimed by the manufacturer.

5.9.4 Main function

The main function of sample storage module shall meet the following requirements:

- a) sending the sample rack mapping information to the software module;
- b) automatic disposal of expired samples;
- c) data interacting with the software module, including storage, disposal, retrieval and others;
- d) internal temperature display and monitoring;
- e) defrosting, frost water collecting and handling;
- f) in place detection of the waste box.

5.9.5 Prompt message

A prompt information shall be sent when the sample storage module has any of the following situations:

- a) the storage is fully loaded;
- b) the error occurs during storage process;
- c) the storage door is opened;
- d) the temperature in the storage is not within the range specified by the manufacturer;
- e) the waste box reaches the capacity limit.

5.10 Software module

The software module shall meet the following requirements:

- a) shall have the information on obtaining the sample test request and the sample location;
- b) should support obtaining the status information of analyzer equipment, reagents, consumables and samples;
- c) shall have the function of issuing sample test and managing test results;
- d) shall have the function of communication with the laboratory information system;
- e) shall have the function of system monitoring to monitor the running status of all the modules in the whole system;
- f) shall have the emergency mode and the function of priority STAT sample handling;
- g) should have the function of automatic quality control;
- h) shall provide system maintenance prompt;
- i) shall have the function of remainder regarding fault, remaining consumables, error status and waste bin status;
- j) shall have the function of user access permission control;
- k) shall have the function of sample retest;
- l) shall have the analyzer-end controlling function, at least include the enabling and disabling functions;
- m) shall have the module controlling function, at least include the function of controlling starting, stopping, enabling and disabling of each module.

5.11 Whole system performance

5.11.1 The overall throughput

Running the whole system, the overall throughput shall not be any lower than the throughput claimed by the manufacturer.

5.11.2 Running accuracy

The operation accuracy rate shall not be lower than 99.99% when running the entire system and launching sample tasks.

5.11.3 Sample tube type

The system shall meet the following requirements:

- a) be compatible with the sample tube specifications claimed by the manufacturer;
- b) Plastic material sample tubes shall be supported.

5.11.4 Noise

The noise shall not exceed 70 dB (A) at the maximum load of the system.

5.11.5 Main function

The main function shall meet the following requirements:

- a) stopping and locating the samples to the connected module and analysis equipment;
- b) sample workload balancing and routing;
- c) have the automatic reset function in case of a recoverable fault;
- d) have a multi-modular connectivity, allowing combination of different modules according to user requirements.

5.12 Appearance

The appearance shall meet the following requirements:

- a) neat appearance, no obvious scratches, cracks and other defects;
- b) the text and signs shall be clear;
- c) the connection of the fasteners shall be firm and reliable, and it shall not be loose.

5.13 Electrical safety requirements

The electrical safety shall comply with the requirements of the applicable clauses in GB/T 42125.1, GB/T 42125.5 and GB/T 42125.14.

5.14 Electromagnetic compatibility requirements

The electromagnetic compatibility shall meet the requirements of the applicable clause in GB/T 18268.1.

5.15 Environmental test

The environmental test shall comply with the requirements of the applicable clause in GB/T 14710.

6 Experimental method

6.1 Normal operating conditions

Electrical requirements: voltage (220 ± 22) V (AC); frequency (50 ± 1) Hz; ambient temperature: 10°C to 40°C; relative humidity: 30% to 80%.

NOTE If the conditions in 6.1 are inconsistent with the product specifications declared by the manufacturer, the product specifications declared shall prevail, and the manufacturer shall explain in the product technical requirements.

6.2 Sample entry module

6.2.1 Capacity

Visually observe the actual placement quantity and determine whether the results meet the requirements of 5.1.1.

6.2.2 Default area capacity

Visually observe the actual placement quantity and determine whether the results meet the requirements of 5.1.2.

6.2.3 Barcode identification accuracy

Run the system, use the declared sample tube barcode type, load at least 10,000 sample tubes with barcode ID for barcode identification instruction verification, to determine whether the result meets the requirements of 5.1.3.

6.2.4 Sample tube cover identification

Run the system, use the module to load at least 10000 covered sample tubes and at least 10000 uncovered sample tubes for identification verification and determine whether the results meet the requirements of 5.1.4.

6.2.5 Barcode identification

Run the system, use the module to load the barcode sample tubes of different coding formats for verification, and determine whether the results meet the requirements of 5.1.5.

6.2.6 Prompt message

Run the system, use the module to execute the sample input, if the error zone is fully loaded, and the barcode ID is repeated, determine whether the results meet the requirements of 5.1.6.

6.3 Centrifuge module

6.3.1 The centrifuge throughput

Adjust the centrifuge to the maximum rotational speed, set the centrifuge for 10 minutes and start the time when the first sample tube is output. 1 hour later determine whether the sample tube count results meet the requirements of 5.2.1.

6.3.2 Relative deviation of rotational speed

Adjust the centrifuge with fully load to the maximum rotational speed for 5 minutes.

The actual rotational speed of the centrifuge is measured with a tachometer with an accuracy of one-thousandth or higher, and the relative deviation of rotational speed B_1 is calculated according to formula (1), determine whether the result meets the requirements of 5.2.2.

$$B_1 = \frac{n-A}{A} \times 100\% \dots \dots \dots (1)$$

Where:

B_1 ----relative deviation;

n ----actual rotational speed (r/min);

A ---maximum rotational speed (r/min).

6.3.3 Rotational speed stability accuracy

Adjust the fully load centrifuge to the maximum rotational speed. After the operation is steady, measure the rotational speed one time in every 5 minutes with a tachometer with an accuracy of one-thousand, for 5 times in total, calculate the average of all results, then the maximum value ($P_{\max}$) and the minimum value ($P_{\min}$) of speed stability accuracy are calculated according to formula (2) and formula (3), Finally determine whether the results meet the requirements of 5.2.3.

$$P_{\max} = \frac{n_{\max} - \bar{n}}{\bar{n}} \times 100\% \dots \dots \dots (2)$$

Where:

$P_{\max}$ ----the maximum value of rotational speed stability accuracy;

$n_{\max}$ ----actual maximum rotational speed (r/min);

$\bar{n}$ ----average rotational speed (r/min).

$$P_{\min} = \frac{n_{\min} - \bar{n}}{\bar{n}} \times 100\% \dots \dots \dots (3)$$

Where

$P_{\min}$ ----the minimum value of rotational speed stability accuracy;

$n_{\min}$ ----actual minimum rotational speed (r/min);

$\bar{n}$ ----average rotational speed (r/min).

6.3.4 Capacity

Visual inspection to determine whether the result meets the requirements of 5.2.4.

6.3.5 Noise

At a distance of 1 meter from the centrifuge in the directions of up, left, right, front, and back, measurements were taken using a sound pressure level meter with A-weighting, the correction method of background noise value in the test is according to 6.4.2 in YY/T 0657-2017 medical centrifuge test method, the maximum value of 5 points is taken as the measurement result to determine whether the result meets the requirements of 5.2.5.

6.3.6 Amplitude

Use a vibrometer or dial indicator to measure in the middle of the centrifuge shell, the maximum value is taken to determine whether the result meets the requirements of 5.2.6.

6.3.7 Temperature rise

The test liquid with the same ambient temperature is put into the centrifuge tube (bottle). After the centrifuge operates under the maximum rotational speed corresponding to the fully load, a temperature measuring device with an accuracy of 1°C is used to measure the difference between the test liquid temperature and the ambient temperature, and determine whether the result meets the requirements of 5.2.7.

6.3.8 Timing device

For the relative deviation of the digital timing device of the centrifuge, test 5 minutes and 60 minutes or nominal maximum timing with a stopmeter with an index value of 1second, measure the deviation between the measured value of the digital timing device and the value displayed by the stopwatch, and determine whether the result meets the requirements of 5.2.8.

6.3.9 Time for speed raising and reduction

The following tests were performed:

- a) Install the measured fully load turning head that can be raised to the highest rotational speed of the centrifuge, and measure with a stopwatch with a separation value of 1second;

- b) Start the centrifuge device, measure the increase time when the centrifuge turns from stationary to the maximum rotational speed, and determine whether the result meets the requirements of 5.2.9;
- c) When the turn of the centrifuge is at the maximum rotational speed, press the stop key to measure the deceleration time required for the turn to drop from the maximum rotational speed to rest, and determine whether the result meets the requirements of 5.2.9.

6.3.10 Main function

Run the system, use this module for functional verification, and determine whether the result meets the requirements of 5.2.10.

6.3.11 Prompt message

Run the system, if the module centrifuge fails or the centrifugal chamber temperature is runaway, visual inspection to determine whether the result meets the requirements of 5.2.11.

6.4 Decapper module

6.4.1 Throughput

Under the premise of sufficient sample supply, the time of decapper the first sample tube is counted as t_0 , and the time of decapper the 100th sample tube is counted as t_1 . Calculate the one-hour throughput ν_1 of the module according to formula (4) to determine whether the result meets the requirements of 5.3.1.

$$\nu_1 = \frac{3600}{t_1 - t_0} \times 100 \dots \dots \dots (4)$$

Where:

ν_1 ----throughput (tube/h);

t_0 ----the time of decapper the first sample tube (s);

t_1 ----the time of decapper the 100th sample tube (s).

6.4.2 Decapping success rate

Run the system, Machine application for $m_1 (m_1 \geq 10000)$ sample tubes, Visually observe that after entering the decapper module, the number of sample tubes that are normally decapped is n_1 , calculate the decapping success rate according to formula (5) to determine whether the result meets the requirements of 5.3.2.

$$P_1 = \frac{n_1}{m_1} \times 100\% \dots\dots\dots (5)$$

Where:

P_1 ----decapping success rate;

n_1 ----the number of normal decapping sample tubes;

m_1 ----the number of sample tubes needs to be decapped on the machine.

6.4.3 Waste box capacity

Run the system, execute this module to visually count the number of discarded pipe covers. When a message indicating the full load threshold of the discarded box appears, record the number of discarded tube caps in the discarded box, and determine whether the result meets the requirements of 5.3.3.

6.4.4 Main function

Run the system, use this module for functional verification, and determine whether the result meets the requirements of 5.3.4.

6.4.5 Prompt message

Run the system and use this module for verification. When the cover fails and the pipe cover box is full, visually observe to determine whether the result meets the requirements of 5.3.5.

6.5 Sample tube division cup module

6.5.1 Throughput

Run the system, under the premise of sufficient sample supply, the time when the first sample tube is put into the division cup module is counted as t_0 (s), the time when the 100th sample tube is put into the cup module is counted as t_1 (s) 。 Calculate the one-hour throughput v_1 of the module according to formula (4) to determine whether the result meets the requirements of 5.4.1.

6.5.2 Volume accuracy and reproducibility of the division cup

Run the system, the minimum sample division cup volume and maximum sample division cup volume claimed by the module, which can be tested according to the following steps:

- a) Raise the cup tube in the electronic balance with a dividing value of 0.01 mg to zero;

- b) Put the split cup tube in the appropriate position, control the liquid dividing needle to add the specified amount of pure water to the container, and then weigh the quality on the electronic balance;
- c) Each division cup volume is measured repeatedly 10 times, the actual amount of added each time is equal to the mass of pure water added divided by the density of pure water at that temperature, and the measured value V_i of each addition is calculated, and calculate the average value $\bar{V}$ and the standard deviation(SD).

Calculate the repeatability CV of 10 measurement results according to formula (6), and determine whether the results meet the requirements of 5.4.2.

Calculate the sampling deviation B_2 according to formula (7), and determine whether the result meets the requirements of 5.4.2.

$$CV = \frac{SD}{\bar{V}} \times 100\% \dots\dots\dots(6)$$

Where:

CV----the coefficient of repeatability variation;

SD----the standard deviation of the measurement results (μL);

$\bar{V}$ ----the average value of the measured value of the added sample (μL).

$$B_2 = \frac{(\bar{V} - V_T)}{V_T} \times 100\% \dots\dots\dots(7)$$

Where:

B_2 ----the sampling deviation;

$\bar{V}$ ----the average value of the measured value of the added sample (μL);

V_T ----the required addition sample volume (μL).

6.5.3 Main function

Run the system, use this module for functional verification, and determine whether the result meets the requirements of 5.4.3.

6.5.4 Prompt message

Run the system, use this module for verification, when the cup division fails or the Tip head is full, visually observe and determine whether the results meet the requirements of 5.4.4.

6.6 Track module

6.6.1 Sample transportation

Run the system, transmit the sample on the track and determine whether the results meet the requirements of 5.5.1.

6.6.2 Track Throughput

- a) Mark the two positions S_1 、 S_2 on the track;
- b) Use a tape measure to measure the distance (mtere) between S_1 and S_2 ;
- c) The time of the sample passing through S_1 position is $t_2(s)$, and the time passing through S_2 position is $t_3(s)$;
- d) The orbital transmission speed v_2 is calculated by formula (8), and determine whether the result meets the requirements of 5.5.2.

$$v_2 = \frac{d}{t_3 - t_2} \dots\dots\dots (8)$$

Where:

v_2 ---the track transmission speed (m/s);

d ---the distance between the two marked positions S_1 and S_2 (m)

t_2 ---the time of the sample passing through S_1 position (s);

t_3 ---the time of the sample passing through S_2 position (s).

6.6.3 Amplitude

Use a vibrometer or dial indicator to measure the track shell and take the maximum value to determine whether the result meets the requirements of 5.5.3.

6.6.4 Prompt message

Run the system, use this module for verification, when the sample carrier movement is blocked or collision, visual observation, to determine whether the results meet the requirements of 5.5.4.

6.7 Interface module

6.7.1 Main function

Run the system, use this module for functional verification and determine whether the result meets the requirements of 5.6.1.

6.7.2 Prompt message

Run the system, use this module for verification, when the sample carrier movement is blocked or collision, visually observeto determine whether the results meets the requirements of 5.6.2.

6.8 Recapper module

6.8.1 Throughput

Run the system, under the premise that the sample is fully supplied, the time of recapper the first sample tube is counted as t_0 , and the time of recapper the 100th sample tube is counted as t_1 . Calculate the one-hour throughput v_1 of the module according to formula (4). and determine whether the result meets the requirements of 5.7.1.

6.8.2 Recapper success rate

Run the system, and when the $m_2(m_2 \geq 10000)$ sample tubes after tested enter the recapper module, the number of normal recaped sample tubes is n_2 . Calculate the recapper success rate according to formula (9). and determine whether the result meets the requirements of 5.7.2.

$$P_2 = \frac{n_2}{m_2} \times 100\% \dots \dots \dots (9)$$

Where:

P_2 ----the recapper success rate;

n_2 ----the number of normal recaped sample tubes;

m_2 ----the number of sample tubes needs to be recapped on the machine.

6.8.3 Main function

Run the system, use this module for functional verification, and determine whether the result meets the requirements of 5.7.3.

6.8.4 Prompt message

Run the system and use this module for verification. When the caps (or film) supply box becomes empty and recap (or sealing film) fails, visually observe and determine whether the result meets the requirements of 5.7.4.

6.9 Sample output module

6.9.1 Capacity

Visually observe the actual number of placements and determine whether the results meet the requirements of 5.8.1.

6.9.2 Main function

Run the system, use this module for functional verification and determine whether the result meets the requirements of 5.8.2.

6.9.3 Prompt message

Run the system and use this module for verification. When the sample frame is full and the grip fails to grab the sample, visually observe and determine whether the result meets the requirements of 5.8.3.

6.10 Sample storage module

6.10.1 Storage temperature

Test according to the method of 6.4.1 in YY/T 0086-2020 to determine whether the result meets the requirements of 5.9.1;

6.10.2 Capacity

Visually observe the actual number of placements and determine whether the result meets the requirements of 5.9.2.

6.10.3 Waste box capacity

Visually observe the number of sample tubes discarded into the discarded box through the discarded command. When the prompt of the discarded box appears, record the number of sample tubes in the discarded box to determine whether the results meet the requirements of 5.9.3.

6.10.4 Main function

Run the system, use this module for functional verification, and determine whether the result meets the requirements of 5.9.4.

6.10.5 Prompt message

Run the system, use this module to simulate the different situations in 5.9.5, and determine whether the results meet the requirements of 5.9.5.

6.11 Software module

Run the system, use this module for functional verification, and determine whether the result meets the requirements of 5.10.

6.12 Whole system performance

6.12.1 The overall throughput

Running the system, under the premise of sufficient supply of the sample tubes, the

sample tube through the Sample entry module, centrifugal module, decapperr module, sample tube division cup module, track module, recapper module, sample output module or sample storage module (or the complete system of declared by the enterprise), and the time starts when the first sample tube enters the sample output module or sample storage module, 1 hour later, record the number of sample tubes into the sample storage module or sample storage module, and determine whether the result meets the requirements of 5.11.1.

6.12.2 Running accuracy

Run the system, loading m_3 ($m_3 \geq 10000$) sample tubes in the Sample entry module, record the number of samples that complete the instructions of all modules of the automatic sample processing system as n_3 , calculate the running accuracy rate P_3 of the system according to formula (10), and determine whether the result meets the requirements of 5.11.2.

$$P_3 = \frac{n_3}{m_3} \times 100\% \dots \dots \dots (10)$$

Where:

P_3 ----the running accuracy rate;

n_3 ----the number of sample tubes to complete the instructions of all modules of the medical automatic sample processing system;

m_3 ----the number of loading system sample tubes.

6.12.3 Sample tube type

Run the system, test the sample tubes of the type declared by the manufacturer, and visual inspection to determine whether the results meet the requirements of 5.11.3.

6.12.4 Noise

At a distance of 1 meter from the whole system in the directions of up, left, right, front, and back, measurements were taken using a sound pressure level meter with A-weighting, and the maximum value of 5 points is taken to determine whether the result meets the requirements of 5.11.4.

6.12.5 Main function

Run the system, use the module for functional verification, and determine whether the result meets the requirements of 5.11.5.

6.13 Appearance

Visually inspect the appearance of the equipment with normal or corrected vision under natural light to determine whether the results meet the requirements of 5.12.

6.14 Electrical safety requirements

Conduct the test according to the methods specified in GB/T 42125.1, GB/T 42125.5 and GB/T 42125.14 to determine whether the result meets the requirements of 5.13.

6.15 Electromagnetic compatibility requirements

Conduct the test according to the method specified in GB/T 18268.1 to determine whether the result meet the requirements of 5.14.

6.16 Environmental test

Conduct the test according to the method specified in GB/T 14710 to determine whether the result meets the requirements of 5.15.

7 Identification, labels, and instructions for use

It shall comply with the requirements of GB/T 29791.3.

8 Packaging, transportation, and storage

8.1 Pack

The packaging and transportation sign shall comply with the provisions of GB / T 191. The packaging containers shall be well sealed, complete, without leakage and damage. The packaging shall protect the system from natural and mechanical damage. Instructions for use shall be attached in the packing box.

8.2 Transportation

Transport as required by the manufacturer.

8.3 Storage

Store according to the requirements specified by the manufacturer.

Bibliography

[1] GB / T 12905 barcode terms
