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INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

WS/T 404.8-2015

Reference intertials for common clinical biochemistry tests. Part 8: Serum amylase

(English Translation)

Issued on: April 21, 2015 **Implemented on: October 1, 2015**

Issued by: National Health and Family Planning Commission of the People's Republic of China

Preview: page 1 of 5 shown, 7 in the full document. Complete English PDF, instant download:
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Table of Contents

Foreword
1 Scope
2 Normative references
3 Terms and definitions
4 Reference interval establishment
5 Reference interval application
5.1 General principles
5.2 Reference interval evaluation, verification and use
5.3 Procedure when the reference interval fails the verification

Foreword

WS/T 404 "Reference Interval of Commonly Used Clinical Biochemical Test Items" is divided into 8 parts.

---Part 1: Serum alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase and gamma-glutamyl transfer Transfer enzyme;

---Part 2: Serum total protein, albumin;

---Part 3: Serum potassium, sodium, and chloride;

---Part 4: Serum total bilirubin, direct bilirubin;

---Part 5: Serum urea and creatinine;

---Part 6: Serum total calcium, inorganic phosphorus, magnesium, iron;

---Part 7: Serum lactate dehydrogenase, creatine kinase;

---Part 8: Serum amylase.

This part is part 8 of WS/T 404.

This section was drafted in accordance with the rules given in GB/T 1.1-2009.

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Preview: page 2 of 5 shown, 7 in the full document. Complete English PDF, instant download:
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Reference interval of common clinical biochemical test items Part 8: Serum Amylase

1 Scope

This part of WS/T 404 specifies the reference interval and application of serum amylase in the Chinese adult population.

This part is applicable to the report and interpretation of serum amylase test results in laboratories of medical and health institutions, and relevant in vitro diagnostic product manufacturers Quotient can also be used by reference.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article Pieces. For undated references, the latest version (including all amendments) applies to this document.

WS/T 402 Establishment of reference interval for clinical laboratory test items

3 Terms and definitions

The terms and definitions defined in WS/T 402 apply to this document.

4 Reference interval establishment

4.1

The reference interval of serum amylase for Chinese adults (20-79 years old) is shown in Table 1.

Table 1 Reference interval of serum amylase in Chinese adult population

Project unit group reference interval Serum amylase (AMY) U/L male/female 35~135

4.2

Refer to Appendix A for information about the process of establishing the reference interval for serum amylase in the Chinese adult population.

5.1 General principles

5.1.1

Clinical laboratories should first consider citing the reference interval of this document.

Note 1: The research workload and cost of establishing the reference interval are huge, and it is

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https://chinastandards.org/standards/ws-t-404-8-2015

more realistic and feasible for clinical laboratories to quote the reference interval than to establish the reference interval by themselves.

Note 2: This reference interval is based on the results of a multi-center study of the Chinese adult population. The test results in the study can be traced to internationally recognized reference methods. See Appendix B.

5.1.2

The necessary verification or evaluation shall be carried out before using the reference interval of this document.

Note 1: The applicability of the external reference interval in the laboratory mainly depends on the comparability of the test results and the applicability of the population when the laboratory and the reference interval are established.

Note 2: Test results only have a constant system bias (correctness of test results) that affects the applicability of the reference interval. Excessive intra-laboratory variation is an experiment the quality of laboratory analysis is not a question of the applicability of the reference interval.

Note 3: The reference interval of this document is established based on the test results of serum. If the type of specimen used by the clinical laboratory is plasma, appropriate evaluation should be performed to determine Decide whether to use this reference interval.

5.2 Reference interval evaluation, verification and use

5.2.1

Perform reference interval evaluation and verification in accordance with the relevant provisions of WS/T 402.

5.2.2

If the laboratory confirmation is comparable to the test results when the reference interval is established and the population is applicable, the reference area of this document can be directly quoted If you are uncertain or need to verify the quoted reference interval based on the requirements of the laboratory management system, you can follow the steps below.

a) There are no less than 20 qualified reference individuals for screening, see A.2.2 for screening criteria;

b) Collect, process, and analyze samples according to the laboratory's operating procedures;

c) Check and eliminate outliers according to appropriate methods (if any, select another reference individual to fill in);

Note: The Dixon method is used for the outlier test. first sort the test results by size and calculate the range R, and then calculate the maximum and minimum values respectively the difference D between its adjacent value; if D/R>=1/3, the maximum or minimum value is regarded as an outlier

Preview: page 4 of 5 shown, 7 in the full document. Complete English PDF, instant download:
https://chinastandards.org/standards/ws-t-404-8-2015

and eliminated; the remaining data is repeated the previous step Carry out outlier test immediately until all outliers are eliminated.

d) If 20 qualified reference individuals are selected, compare the 20 test results with the reference interval. If the data beyond the reference interval does not exceed If there are more than 2, then the verification is passed; if there are more than 2, then another 20 qualified reference individuals will be selected and re-inspected in accordance with the above judgment standards.

certificate. If there are more than 20 reference individuals and the data exceeding the reference interval does not exceed 10%, the verification is passed; if the data exceeds 10% If the reference interval is exceeded, at least 20 qualified reference individuals shall be selected and re-verified in accordance with the above judgment standards. Validation results If it meets the requirements, the reference interval can be used directly, otherwise the reason should be found.

5.3 Procedure when the reference interval fails the verification

5.3.1

In the case of failure to pass the verification, the analysis quality, especially the accuracy, should be evaluated first, if it is confirmed that the analysis quality is caused by the detection system Problems, the analysis system should be improved or replaced. Analysis quality evaluation can adopt (but not limited to) the following methods.

a) Analyze interchangeable certified reference materials or other suitable reference materials;

b) Participate in the appropriate accuracy verification plan or standardization plan;

c) Compare with other systems or methods with reliable performance.

5.3.2

If it is proved that it is due to population reasons (such as ethnicity, high altitude areas, special living habits, etc.), the verification should be carried out according to WS/T 402 the requirements for establishing or citing appropriate reference intervals.

Appendix A

(Informative appendix) Information about the process of establishing the reference interval A.1 Steps to establish reference interval the reference interval of this document is established in accordance with the requirements of WS/T 402 using a multi-center research method, which mainly includes the following steps.

a) Select reference individuals to form a reference sample group;

b) Collect and process blood samples to obtain serum samples;

Preview: page 5 of 5 shown, 7 in the full document. Complete English PDF, instant download:
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