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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS/T 404.4-2018

**Reference intervals for common clinical biochemistry tests -
Part 4: Serum total bilirubin and direct bilirubin
(English Translation)**

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Foreword

WS/T 404 "Clinical Common Biochemical Test Project Reference Interval" is divided into 8 parts.

- Part 1. Serum alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase, and gamma-glutamyl transfer Enzyme
- Part 2. serum total protein, albumin;
- Part 3. Serum potassium, sodium, chlorine;
- Part 4. Serum total bilirubin, direct bilirubin;
- Part 5. Serum urea, creatinine;
- Part 6. Serum total calcium, inorganic phosphorus, magnesium, iron;
- Part 7. serum lactate dehydrogenase, creatine kinase;
- Part 8. Serum amylase.

This part is the fourth part of WS/T 404.

This part is drafted in accordance with the rules given in GB/T 1.1-2009.

1 Scope

This part of WS/T 404 specifies the reference interval for serum total bilirubin and direct bilirubin in Chinese adult population and its application.

This section applies to the report and explanation of the results of serum total bilirubin and

direct bilirubin test in the laboratory of medical and health institutions, relevant in vitro diagnosis Manufacturers can also refer to the use.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

Development of reference intervals for WS/T 402 clinical laboratory test items

3 Terms and definitions

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

4 Reference interval

4.1

The reference range of serum total bilirubin and direct bilirubin in Chinese adult population (20-79 years old) is shown in Table 1.

Table 1 Reference interval of serum total bilirubin and direct bilirubin in Chinese adult population

Project grouping

Reference range

(mol/L)

Serum total bilirubin (TBIL) Male ≤ 26.0 Female ≤ 21.0 Male/female ≤ 23.0 Serum direct bilirubin (DBIL) System a ≤ 8.0 System b, c ≤ 4.0

Note 1: Direct bilirubin does not have an internationally accepted metrology traceability standard, so this document currently provides a system-specific reference interval.

Note 2: System a. Roche supporting system; System b. Beckman DXC series supporting system; System c. Beckman AU series supporting system, all of which are diazo method. table the analysis system is listed in order to facilitate the laboratory to reasonably quote the appropriate reference interval or reference interval transfer, and does not indicate that these Product recognition.

4.2

See Appendix A for information on the establishment of the reference interval for serum total bilirubin and direct bilirubin in Chinese adult population.

5.1 General principles

5.1.1

The clinical laboratory should prefer the reference interval for this document.

Note 1: The reference workload establishes the research workload and cost, and the clinical laboratory reference interval is more objective and feasible than the establishment of the reference interval.

Note 2: This reference interval is based on the results of the multi-center study of the Chinese adult population. The results of the total bilirubin test in the study can be traced back to internationally accepted reference methods or targets.

See Appendix B for quasi-substances.

Note 3: There is no internationally recognized metrology traceability of direct bilirubin. Users who do not have a reference interval in this document can transfer reference intervals.

Used on the basis of verification.

5.1.2

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

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

Note 2: Only a constant system bias (correctness of test results) affects the applicability of the reference interval. Excessive intra-laboratory variation is true.

The laboratory analyzes the quality problem, not the reference interval applicability problem.

Note 3: The reference interval of this document is based on the results of serum tests. If the type of specimen used in clinical laboratories is plasma, an appropriate assessment should be made.

Whether to use this reference interval.

5.2 Evaluation, verification and use of reference intervals

5.2.1

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

5.2.2

If the laboratory confirms that the test results are comparable to the reference interval and the population is applicable, the reference interval of this document can be directly quoted.

If you are unsure or need to verify the referenced reference intervals based on the requirements of the laboratory management system, you can do the following.

- a) screening not less than 20 qualified reference individuals, see A.2.2 for screening criteria;
- b) Collect, process and analyze samples according to the laboratory procedures;
- c) check and eliminate outliers in an appropriate manner (if available, select additional reference individuals);

Note: The outlier test uses the Dixon method. first, the test results are sorted by size and the range R is calculated, and then the maximum and minimum values are respectively calculated.

The difference between the values D; if $D/R \geq 1/3$, the maximum or minimum value is regarded as the outlier value; the remaining data is repeated for the outlier detection Test until all outliers are removed.

- d) If 20 qualified reference individuals are selected, compare 20 test results with the reference interval, if the data beyond the reference interval is not exceeded If there are 2, then pass the verification; if there are more than 2, then another 20 qualified reference individuals will be tested according to the above criteria.

certificate. If there are more than 20 reference individuals, if the data beyond the reference interval does not exceed 10%, the verification is passed; if more than 10% of the data is exceeded for the reference interval, select at least 20 qualified reference individuals and re-verify according to the above criteria. Verification result If the requirements are met, the reference interval can be used directly, otherwise the reason should be found.

5.3 Handler when the reference interval fails verification

5.3.1

For cases that have not been verified, the quality of the analysis, especially the accuracy, should be evaluated first, if it is confirmed that the quality of the analysis is caused by the detection system.

Problem, the analysis system should be improved or replaced. Analytical quality assessment can be used, but is not limited to the following.

- a) analysis of interoperable certified reference materials or other suitable reference materials;
- b) participate in a suitable accuracy verification plan or standardization plan;
- c) Compare with other systems or methods with reliable performance.