

ICS 03.120.00
CCS A 00

QC

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

QC/T 502-2025

**Metallographic examination for steel automobile parts by
induction hardened
(English Translation)**

Issued on: August 26, 2020

Implemented on: December 1, 2020

Issued by: Certification and Accreditation Administration

Table of Contents

Foreword...	3
1 Scope...	4
2 Normative references...	4
3 Terms and definitions...	4
4 Method validation...	8
4.1 General...	8
4.2 Selection of characteristic parameters...	9
4.3 Validation method...	9
4.4 Validation of characteristic parameters...	11
5 Method verification...	17
5.1 General...	17
5.2 Selection of characteristic parameters...	17
5.3 Qualitative method...	18
5.4 Quantitative method...	18

1 Scope

This Standard provides laboratory guidance for method verification and validation of microbiological testing methods.

This Standard applies to method verification of methods developed by laboratories, standard methods used beyond their intended scope, and expanded and modified standard methods. It is also suitable for method validation before the official use of newly introduced standard methods in laboratories.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 16140-2, Microbiology of the food chain-method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

ISO/IEC Guide 99: 2007, International vocabulary of metrology - Basic and general concepts and associate terms (VIM)

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in ISO/IEC Guide 99:2007 and ISO/IEC 17025:2017 as well as the followings apply.

3.1

method verification

Through verification or testing, the laboratory provides objective evidence to prove that the requirements specified in the testing method are met. That is to provide objective evidence to prove that the laboratory can correctly apply the method and ensure that the required method performance is achieved.

NOTE 1: Where applicable, measurement uncertainty shall be considered.

NOTE 2: It is adapted from ISO/IEC Guide 99:2007, Definition 2.44.

3.2

method validation

Through testing, the laboratory provides objective evidence that the method to be determined meets the intended use.

NOTE 1: Method validation shall identify the factors that affect method performance and their degree of influence, verify the performance characteristics of the method, and determine the matrix to which the method is applicable and the limitations of its use.

NOTE 2: Validation may include validation of sampling, handling and transportation procedures for test items.

NOTE 3: It is adapted from ISO/IEC Guide 99:2007, Definition 2.45.

3.3

reference method

Methods that are recognized and widely accepted by international, national, industry or organizations.

NOTE: The reference method gives priority to the methods recommended by the International Organization for Standardization (ISO), Chinese National Standards (GB), and the Association of

Analysts International (AOAC). Other industry accepted methods may also serve as reference methods.

3.4

qualitative method

An analytical method that detects the presence of target microorganisms using direct or indirect methods.

3.5

quantitative method

An analytical method that measures the number of target microorganisms directly (such as counting a certain mass or volume of samples) or indirectly (such as absorbance value, impedance, etc.) on a certain number of samples.

3.6

confirmatory method

A method that can provide all or part of the information on the target, based on which information can be clearly identified and, if necessary, quantified at the concentration level of concern.

3.7

screening method

A method that has the ability to efficiently process large numbers of samples and is used to detect the presence of a substance or group of substances at a concentration level of interest.

NOTE: These methods are used to screen large numbers of samples for possible positive results and to avoid false negative results. The detection results obtained by such methods are usually qualitative results or semi-quantitative results.

3.8

sensitivity

The ability of a reference method or method to be validated to detect an analyte.

3.9

relative trueness; RT

The same sample is tested using the validation method and the reference method to see how consistent the results are. That is, the sum of the number of validated positives and the number of negative validated by both the method to be validated and the reference method is divided by the total number of samples used for validation.

3.10

level of detection; LOD_x

Using a microbial qualitative detection method, through a given detection step, the content of the measured analyte is obtained with a probability x of a positive detection result.

Example: LOD50 means the level of detection at which 50% of tests give positive results.

[ISO 16140-1:2016, Definition 2.35]

3.11

relative level of detection; RLOD

For the same sample, the ratio of the level of detection (LOD x) of the validated method and the reference method.

3.12

estimated LOD50

LOD50 (positive result detection probability of 50%) is determined based on the experimental design described in this Standard.

NOTE: Due to the very small number of test samples, the LOD50 cannot be determined accurately.

Therefore, the term estimated LOD50 is used.

3.13

inclusivity study

Research on qualitative or quantitative detection of purified target bacteria using methods to be validated.

[ISO 16140-1:2016, Definition 2.31]

3.14

exclusivity study

Research on purified non-target bacteria using a method to be validated. These non-target strains may be cross-reactive, but will ultimately not be qualified or quantified difference between a specified value of a quantitative result and the mean of repeated measurements.

[ISO 16140-1:2016, Definition 2.9]

3.20

estimated bias

Bias determined based on the experimental design described in this Standard.

NOTE: Due to the very small number of samples tested, bias cannot be accurately determined.

Therefore, the term estimated bias is used.