

**NORMATIVE INSTRUCTION - IN Nº 121, OF MARCH 9, 2022**

**(Published in DOU No. 51 of March 16, 2022)**

It provides for the criteria for acceptance of test reports required for the analysis of applications for notification and registration of sanitizing products and provides other measures.

The Collegiate Board of the National Health Surveillance Agency, in the use of the attribution conferred on it by article 15, III and IV allied to article 7, III and IV of Law No. 9,782, of January 26, 1999, and to article 187, VII, § 1 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 585, of December 10, 2021, at a meeting held on March 9, 2022, resolves:

Art. 1 In the requirements for notification and registration of sanitizing products and their changes, ANVISA only accepts the reports of tests performed by laboratories that are qualified in the Brazilian Network of Analytical Health Laboratories (REBLAS), as provided for in the Collegiate Board Resolution - RDC No. 390, of May 26, 2020, or its updates.

Single paragraph. Only efficacy test reports that have been issued by laboratories recognized in accordance with the Principles of Good Laboratory Practice (GLP) are accepted.

Art. 2 Reports of tests carried out by foreign laboratories are also accepted, provided that:

- recognized in accordance with the principles of Good Laboratory Practice (GLP) by monitoring authorities of member countries of the Organization for Economic Cooperation and Development (OECD) or non-members of the OECD that have full adherence to the acts of that organization for mutual acceptance of data; or
- accredited by an accreditation body that is a signatory to the agreement of the International Laboratory Accreditation Cooperation (ILAC) or Inter American Accreditation Cooperation (IAAC).

Art. 3 The test reports covered by this Normative Instruction must contain, at least, the following information:

- I - title or identification of the document;
  - II - Name and address of the applicant;
  - name and address of the laboratory and place where the tests were carried out
- Held;

- the date of receipt of the samples, the start and end of the tests and the issuance of the test report;
- identification and quantity of the sample received;
- complete qualitative-quantitative composition of the sample tested; VII - batch, date of manufacture and validity of the sample tested;
- VIII - identification of the method used and test conditions; IX - acceptable reference values for the sample tested;
- X - results of the analysis with the units of measurement, where appropriate; XI - detailed conclusion of the test reports;
- unambiguous identification of the items tested;
- identification and signature of the persons authorized to issue the analysis report; and
- unambiguous identification of the test report inserted on all pages to ensure that they are recognised as an integral part of the same report, and a clear identification of the end of the report.

Single paragraph. The test reports shall be submitted in original form or in duplicate.

Art. 4<sup>o</sup> Test reports issued until October 1, 2013, are exempt from compliance with the provisions of article 3.

Art. 5 The following are hereby revoked:

- Normative Instruction No. 04 of July 2, 2013, published in the Official Gazette No. 126, of July 3, 2013, Section 1, p. 35; and
- Normative Instruction No. 12, of October 11, 2016, published in the Official Gazette No. 197, of October 13, 2016, Section 1, p. 42.

Art. 6 This Normative Instruction enters into force on April 1, 2022.

**ANTONIO BARRA TORRES**