

COMMISSARIO STRAORDINARIO PER L'ATTUAZIONE E IL COORDINAMENTO DELLE MISURE DI CONTENIMENTO E CONTRASTO DELL'EMERGENZA EPIDEMIOLOGICA COVID-19

CALL FOR TENDER IN SIMPLIFIED AND URGENCY PROCEDURE TO PURCHASE KITS, REAGENTS AND CONSUMABLES FOR CARRYING OUT 150,000 SEROLOGICAL TESTS FOR A SAMPLE SURVEY ON SARS CoV-2 INFECTION SPREAD

1. Information concerning the Contracting Authority and the Procurement Process:

The Extraordinary Commissioner for the implementation and coordination of measures to contain and combat the epidemiological emergency by COVID-19 calls for this simplified competitive procedure (hereinafter: "Extraordinary Commissioner for COVID-19 Emergency" or "contracting entity"), under Art. 122 of Law Decree 17 March 2020, No. 18, as defined below:

- Competitive procedure, open to companies producing the required medical supplies, by means of this "call" notice, published on the institutional web sites of the Ministry of Health, the Presidency of the Council of Ministers – The Extraordinary Commissioner, and the Department of Civil Protection, effective for five days, and in any case no later than April 22, 2020;
- Online tender submission by the same date;
- Evaluating tenders by the selection board, with the terms and procedures stated in point No.
 8 and on the basis of the evaluation criteria referred to in point No. 7;
- Subsequent signing of the supply contract by April 29, 2020.

As regards this procedure, the following references are essential:

- Contact person, in charge of the procedure: Dr. Antonio Fabbrocini, Offices of the Extraordinary Commissioner for COVID-19 Emergency;
- For any communication or request for clarifications, please refer to: <u>commissarioemergenzacovid19@governo.it</u>, explicitly indicating: "simplified procedure for purchasing serological kits"
 - Means of transmission for tenders: by certified e-mail at: commissarioemergenzacovid19@pec.governo.it

2. Nature and purpose of the procedure:

This is a simplified, urgent competitive procedure, by way of derogation from the provisions of the Code of Public Contracts (Legislative Decree No. 50 of 18 April 2016), and concerns the urgent supply of CLIA and/or ELISA Kits for the detection of specific IgG (SARS - CoV-2 neutralizing antibodies), reagents and consumables, to carry out 150,000 serological tests for a sample survey on SARS COV-2 infection spread, having high quality, functionality and speed characteristics, adequately validated by qualified laboratories or regulatory agencies, at national or international level, with possible subsequent extension of the provision of kits, reagents and consumables of the same type, for carrying out additional 150,000 tests.

3. Qualitative requirements of goods concerning the procedure:

The essential characteristics of the products covered by the procedure are the following:

- a) The type of Kits shall be CLIA and/or ELISA, for the detection of specific IgG (SARS CoV-2 neutralizing antibodies), and related reagents;
- b) Testing validation by qualified laboratories or regulatory agencies operating at national or international level;
- c) Testing specificity no lower than 95%;
- d) Testing sensitivity no lower than 90 %;
- e) Suitability of the tests for a large-scale application (by means of the contracting out of the analyses to a large number of accredited labs operating in the area, with no need for further training);
- f) A quick testing response (with the possibility, inter alia, of simultaneously processing at least 120 tests per hour);
- g) A quick transport and delivery, starting from May 3, 2020;
- h) The willingness to supply additional quantities of the products covered by the procedure, with the specification of the pertinent conditions and timing.

The absence of the validation referred to in letter b) and the other fundamental requirements referred to in letters c), d), e), f), g), as well as the offer of products other than those required in letter a), are express conditions for exclusion from the tender.

4. Subjective requirements of the economic operators concerned:

The same integrity and reliability requirements, as provided for in the Code of Public Contracts (Legislative Decree No. 50 of 18 April 2016), are required demonstrable, in view of the urgency, also by means of self-certification.

Failure to meet the requirements set out in Art. 80 of the aforementioned Code shall also cause the exclusion from the tender.

5. How to submit tenders:

Tenders, accompanied by the required documentation, shall be sent, in PDF format, to the "Extraordinary Commissioner for COVID-19 emergency", exclusively by certified e-mail: commissarioemergenzacovid19@pec.governo.it.

The document containing the qualitative tender (description of products and their qualitative requirements as indicated sub 3)) and the one containing the economic offer must be signed by qualified electronic signature.

6. The Tender Committee:

The Tender Committee shall evaluate the tenders submitted. The Committee is appointed by the Extraordinary Commissioner for COVID-19 Emergency and is composed of:

- a) two experts appointed by the Technical-Scientific Committee set up at the Civil Protection Department for COVID-19 emergency;
- b) A representative of the Ministry of Health (belonging to the competent ministerial structure);
- c) Two legal experts, of which one as Chairman of the Committee;
- d) A member from the structure of the Extraordinary Commissioner for COVID-19 emergency, acting as secretary and without voting rights.

In the tender process, if required, the Committee can make use of the Technical-Scientific Committee set up at the Civil Protection Department for COVID-19 Emergency.

The works of the Committee may take place in videoconference or teleconference.

7. Tender evaluation criteria:

The tender evaluation criteria for the admission to selection stage are based on:

- Product quality (sub criteria: level of validation of the tests, percentage of specificity and percentage of sensitivity, above the minimum required);
- Simplicity and speed of analysis processes (sub-criteria: large-scale applicability, quick response, high processability, properly documented);
- Promptness in delivery;
- Price:
- Any additional elements of the tender.

More specifically, the score obtained from each single tender, admitted to the evaluation stage, shall follow a predetermined algorithm $P=(c^*0,30+d^*0,30+e^*0,20+f^*0,10+g^*0,10)$ / 1, where c, d, e, f, g are the requirements referred to sub. 3, whether the exclusion conditions under sub. 3 are not met. Please note that, in the case of equal score, the tender with the best economic conditions and, in any case, the one that should provide for the supply of kits and reagents free of charge shall be favoured.

8. Tendering process rules:

The evaluation of tenders shall be carried out in three sequential stages, to be concluded, no later than April 29:

- Assessment of the general eligibility requirements on the basis of the documentation submitted, starting from April 22 and within April 23;
- Verification of tenders' consistency with respect to the object of the present Call, to be carried
 out by the Technical-Scientific Committee, with the immediate exclusion of inadmissible
 tenders because they are not consistent or in any case lower than the minimum
 requirements, referred to sub. 3, from April 22 and within April 24;
- Evaluation of eligible tenders, according to the criteria indicated in the present Call, from April 25 and within April 28;
- Awarding and definition of the ranking by April 29.

In the event that some tenders admitted to the third stage achieve a particularly high evaluation, they may be mentioned by the Committee, and in any case considered compatible with the fulfilment of requirements set out in this procedure.

9. Immediate and express termination clause of the contract:

The supply of products which, for each 100 received kits, reagents and consumables, should not comply with the quality requirements requested and/or declared, results in the immediate and express termination of the contract, under Art. 1456 of Civil Code, with charges to be borne by the supplier, without prejudice to any right to compensation.

THE EXTRAORDINARY COMMISSIONER
FOR COVID 19 EMERGENCY
Dott. Domenico Arcuri