English translation for convenience only

ANSWERS TO CLARIFICATION QUERIES APRIL 21st, 2020 – Part 2

TENDER CALLING WITH SIMPLIFIED PROCEDURE AND OF MAXIMUM URGENCY REGARDING THE ACQUISITION OF KITS, REAGENTS, AND CONSUMABLES FOR THE PERFORMANCE OF 150.000 SEROLOGICAL TESTS AIMED AT OBTAINING A SAMPLE SURVEY ON THE DISSEMINATION OF THE SARS-COV-2 INFECTION

NUMBER	QUESTION	ANSWER
23	Must the medical device in question be registered with the ministry of health or is it sufficient that it is "validated" in order to be eligible to participate in the call?	As reported in the call on point 3b, it is sufficient that there is "a validation of the tests by qualified laboratories or regulatory agencies operating at national or international level".
24	Will any offers for a test (ELISA method) be taken into consideration without CE mark for temporal reasons?	As specified in the call, at the time of evaluation all serological tests of the CLIA type (or CMIA equivalent) and/or ELISA will be taken into consideration without the need for a CE mark.
25	In your call, there is no clear reference for which type of serological test you need: Are you looking for a conventional PCR test or rapid tests with results within 15 minutes?	The type of kit needed is the one that refers to serological tests of the CLIA type (or the equivalent for CMIA) and/or ELISA. Tests aimed at identifying the viral RNA are not the aim of the call.
26	For what it concerns the procedure, we ask you to extend the participation in the call not only to producers but also to suppliers of CE marked products that are already evaluated by reference centers, since, in Italy, there is only one CLIA and ELISA manufacturer.	An importing company can activate the initiative on behalf of the producer and possibly be authorized by it to present the offer as its agent, remembering that the technical and economic capacity of the manufacturing company must be certified as much as the agent one.
27	Since the acquisition of kits, reagents, and consumables for 150,000 serological tests requires that the type of kit is CLIA and/or ELISA, can we respond to the offer with our RDT?	We are looking for serological tests based on CLIA (or CMIA equivalent) and/or ELISA methods to be used on serum samples and not on capillary blood.
28	I would like to point out that the specific request for CLIA and/or ELISA kits combined with the detection	IgM are, by definition, immunoglobulins with transient permanence in the peripheral blood of an individual. For a seroprevalence study in which we primarily

	of IgG only strongly inhibits the possibility of an offer, which is limited, as far as I am aware, to a single supplier. Therefore, I ask you to admit to the test other IgM modalities other than CLIA and ELISA, otherwise you risk to cut off a large part of manufacturers and limit the competition and value of the sample survey requested in the call.	want to check the percentage of subjects who have been exposed to SARS-COV-2 it was given priority to specific IgGs. If a test also determines the IgM this does not represent a penalizing factor.
29	1. Specify why, since it is an epidemiological evaluation, the dosage is required only for specific IgG and not also for IgM 2. Also specify the dosage method: quantitative, qualitative, or semi-quantitative 3. Specify how many and which laboratories on the national territory will be involved in the dosage activity; this request is motivated by the need to organize the instrumental support and the related specialist technical assistance 4. You are requested to specify the order receipt, shipping and delivery methods. In addition to this, please specify the quantities expected for shipments based on a weekly/ monthly or other requirement basis.	1. IgM are, by definition, immunoglobulins with transient permanence in the peripheral blood of an individual. For a seroprevalence study in which we primarily want to check the percentage of subjects who have been exposed to SARS-COV-2 it was given priority to specific IgGs. If a test also determines the IgM this does not represent a penalizing factor. 2. As is it not specified in the call, this is not a prequalification criterion. 3. There must be at least one laboratory per region or autonomous province capable of performing the test. 4. Please refer to point 3 letter g of the call.
30	In point f) of the quality requirements of the goods requested in the call, we ask you to indicate “the speed of response of the tests (with, among others, the possibility of processing at least 120 tests per hour)”. We would like clarification regarding “the possibility of processing at least 120 tests per hour”, also depending on the organization and on the test execution activity by the staff of the Body, therefore not corresponding to the response times of the test.	For greater clarification concerning answer no.10, the instrumentation necessary for the realization of the serological test must be able to process at least 120 tests per hour, regardless of the organization of the test execution activity by the staff of the Body.