Frequently Asked Questions (FAQs) relating to new Chagas screening and confirmatory testing requirements as part of new deceased donor screening of endemic diseases requirements

Chagas screening testing FAQs

Q: Which tests are eligible for use for the Chagas Screening Test requirement?

Testing must be performed using a Food and Drug Administration (FDA) licensed, approved, or cleared donor screening test for T. cruzi antibody. OPOs may consult with their commercial laboratory, FDA guidance, or the test manufacturer if they are unsure if a specific test has been approved for donor screening.

Q: Is there a requirement for when OPOs must perform the Chagas screening test?

It is recommended that the screening test be collected prior to transplant or recovery so that appropriate recipient monitoring can be put into place while awaiting confirmatory results. However, the policy does not include a requirement for screening test results to be available prior to transplant. This requirement was removed from the policy post-public comment in order to appropriately balance preventing delay in allocation and patient safety. The Committee recognizes that Chagas disease is treatable if transmitted to a recipient if it is identified and treated early.

Confirmatory testing results do not need to be available prior to transplant. In the event of a positive screening result, programs should implement monitoring programs for recipients until confirmatory results are received.

Q: Which donors are impacted by the new Chagas testing requirements?

Donors whose history reflects the donor's birthplace was in a country classified as endemic for Chagas disease by the CDC at the time of testing. The OPTN maintains a list of these countries, and this list will also be provided within the OPTN computer system after implementation.

Q: Has the risk for Chagas disease in the United States changed?

No. Recent media articles have highlighted the presence of Chagas in certain parts of the United States and brought a heightened awareness of this disease. However, the risk of Chagas is still low in the United States. Donors born in the United States are not subject to

the new testing requirements. The screening and testing requirements apply only to donors born in countries listed as endemic for Chagas here.

Q: What must an OPO do if the initial Chagas screen is negative?

OPOs should enter this result in the OPTN Computer System. No further confirmatory or screening testing is required if the initial screening result is negative. See the education model in UNOS Connect for more details on how changes to Chagas screening and testing have been implemented. The course number and title are: *SYS200: Expanding Deceased Donor Evaluation Testing for Endemic Diseases*

Q: What must an OPO do if the initial Chagas screening test is positive?

Within 72 hours of receipt of a positive T. cruzi antibody donor screening test, the OPO must submit a sample for confirmatory testing. Confirmatory testing requires the performance of at least two FDA licensed, approved, or cleared antibody diagnostic tests.

Chagas confirmatory testing FAQs

Q: Which tests can be used to meet the confirmatory testing requirement?

Any FDA licensed, approved, or cleared antibody diagnostic tests may be used to meet the confirmatory testing requirement. The OPTN does not maintain a list of all approved tests. OPOs should consult their commercial lab, FDA guidance, or the test manufacturer if they are unsure if a specific test has been approved for diagnostic testing.

Q: What is the benefit of two confirmatory tests?

For the purpose of clinical diagnosis, no single assay has sufficient sensitivity and specificity to be solely relied on, therefore two serological tests based on different antigens (e.g. whole parasite lysate and recombinant antigens) and/or techniques (e.g. EIA and IFA, or EIA and RIPA) are used in parallel to increase the accuracy of the diagnosis.

Q: Can OPOs submit a sample to the CDC for confirmatory testing?

Yes, per policy OPOs may submit a sample to the CDC for confirmatory testing. However, there have been changes to CDC processes since the time of policy finalization and it is recommended that OPOs utilize commercial laboratories instead of the CDC if the OPO is unable to perform two confirmatory tests. The OPTN is exploring how to best update or

clarify policy to reflect current CDC processes. Members may contact member.questions@unos.org with additional questions.

Q: Does CDC perform two confirmatory tests?

There have been changes to CDC processes since the time of the policy finalization. Today the CDC testing involves only one confirmatory test, which is not sufficient to diagnose Chagas disease. While, per policy, OPOs may still submit a sample to the CDC, OPOs may find it more practical to utilize commercial laboratories which can perform two simultaneous confirmatory tests for Chagas.

If submitting a sample to the CDC, and a positive test result is returned, an additional confirmatory test is required to accurately confirm a Chagas diagnosis. The OPTN is exploring how to best update or clarify policy to reflect current CDC processes. Members may contact member.questions@unos.org with additional questions.

If a sample is sent to the CDC for confirmatory testing and the result is negative, no additional testing is needed to confirm the negative result.

Q: May an OPO use the same test kit for confirmatory testing that was used for the initial screen?

No. The screening testing for Chagas does not have adequate sensitivity and specificity to diagnose Chagas and cannot be used again as a confirmatory test. Two different antibody diagnostic tests are required for confirmatory testing.

Q: May the OPO use the same sample for confirmatory testing that was used for the initial screening test?

Yes. The same sample may be submitted for multiple tests.

Q: May the OPO use the same sample for both confirmatory tests?

Yes. The same sample may be submitted for multiple tests.

Q: When must the sample be submitted for confirmatory testing?

A sample must be submitted within 72 hours of receipt of a positive screening test.

Q: Does a sample for confirmatory testing need to arrive at the lab within 72 hours of receipt of a positive screening test?

No. A sample that has been collected or is in transit to a lab would meet the policy requirement.

Q: When do these new requirements start?

The policy implementation date is October 1, 2025.

Q: How will these changes be reflected in the OPTN computer system?

See the education model in the OPTN Learning Management System known as UNOS Connect for more details on how changes to Chagas screening and testing have been implemented. The course number and title are: **SYS200: Expanding Deceased Donor Evaluation Testing for Endemic Diseases**