Test Definition: CHIDB

Chimerism-Donor

Overview

Useful For

Evaluating the donor cells prior to bone marrow transplant

Determining the relative amounts of donor and recipient cells in a specimen.

An indicator of bone marrow transplant success

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
ADONO	Additional Chimerism Donor	No	No

Testing Algorithm

Complete chimerism analysis requires 3 specimens for 3 separate tests listed below. These specimens should be submitted when collected. An interpretive report will be provided once all specimens are received.

-CHRGB / Chimerism-Recipient Germline (Pretransplant), Varies

-CHIDB / Chimerism-Donor, Varies

-CHIMU / Chimerism Transplant No Cell Sort, Varies or CHIMS / Chimerism Transplant Sorted Cells, Varies

Billing occurs with the following tests:

-CHRGB / Chimerism-Recipient Germline (Pretransplant), Varies; for pre-transplant and donor specimens

-CHIMU / Chimerism Transplant No Cell Sort, Varies; for unsorted post-transplant specimens

-SORT1 / Chimerism Cell Sort 1 (Bill Only) and/or SORT2 / Chimerism Cell Sort 2 (Bill Only); for sorted post-transplant specimens. ordered under CHIMS / Chimerism Transplant Sorted Cells, Varies

If an additional donor specimen is submitted, ADONO / Additional Chimerism Donor (Bill Only) will be performed at an additional charge.

See Chimerism-Recipient Germline Testing Algorithm in Special Instructions.

Special Instructions

- Buccal Swab Collection Instructions
- Chimerism Analysis Information Sheet
- Chimerism-Recipient Germline Testing Algorithm

Method Name

Polymerase Chain Reaction (PCR) Amplification/Capillary Electrophoresis

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

This test is for the pre-bone marrow transplant evaluation of the donor specimen.

Additional Testing Requirements

In addition to this test, complete chimerism analysis also requires specimen submission for the following:

-CHRGB / Chimerism-Recipient Germline (Pretransplant)

-CHIMU / Chimerism Transplant No Cell Sort, Varies or CHIMS / Chimerism Transplant Sorted Cells, Varies

These tests must be ordered on both the pre- and post-specimens under separate order numbers. The 3 specimens do not need to be submitted at the same time.

Shipping Instructions

1. Specimen must arrive within 7 days of collection.

2. Collect and package specimen as close to shipping time as possible.

Necessary Information

The following information is required:

1. Pertinent clinical history

2. Specimen source

3. Donor identifier and donor date of birth

4. Donor date of collection

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Blood

Container/Tube:

Preferred: Lavender top (EDTA)

Acceptable: Yellow top (ACD)

Specimen Volume: 6 mL

Collection Instructions:

1. Invert several times to mix blood.

2. Send specimen in original tube. **Do not** aliquot.

3. Label specimen as blood.

Specimen Type: Bone marrow

Container/Tube:

Preferred: Lavender top (EDTA)

Acceptable: Yellow top (ACD)

Specimen Volume: 2 mL

Collection Instructions:

1. Invert several times to mix bone marrow.

2. Send specimen in original tube. **Do not** aliquot.

3. Label specimen as bone marrow.

Specimen Type: Buccal swab

Supplies: Buccal Swab Kit (T543)

Container/Tube: Buccal smear collection kit

Specimen Volume: 2Cyto-Pakbrushes-1 per cheek

Collection Instructions:

1. Patient should rinse out mouth vigorously with mouthwash for approximately 15 seconds.

2. Remove Cyto-Pakbrush from container only touching "stick" end. Save container.

3. Using **medium** pressure, rotate brush several times on inside of cheek.

4. Return brush to container and cap.

5. Repeat steps 2 through 4 on other cheek using second brush.

6. It is important that patient's buccal cells are not contaminated with cells from any other source. Do not touch bristles. Do not brush too vigorously. If blood appears, discard brush and restart collection process.

7. Label each container with patient's name and order number or hospital/clinic number.

Additional Information: It is important that the cells do not dry out during shipping. Ensure that container is tightly sealed.

Forms

1. Chimerism Analysis Information Sheet (T594) in Special Instructions

2. If not ordering electronically, complete, print, and send a Hematopathology/Cytogenetics Test Request (T726)) with the specimen.

Specimen Minimum Volume

Blood: 3 mL
Bone Marrow: 2 mL
Lesser volumes may be acceptable, depending on white cell count.
Call 800-533-1710 or 507-266-5700 with questions.

Reject Due To

Gross hemolysis	Reject
Moderately to severely clotted	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)	7 days	
	Refrigerated	7 days	

Clinical and Interpretive

Clinical Information

Patients who have had donor hematopoietic cells infused for the purpose of engraftment (ie, bone marrow transplant recipients) may have their blood or bone marrow monitored for an estimate of the percentage of donor and recipient cells present. This can be done by first identifying unique features of the donor's and the recipient's DNA prior to transplantation and then examining the recipient's blood or bone marrow after the transplantation procedure has occurred. The presence of both donor and recipient cells (chimerism) and the percentage of donor cells are indicators of transplant success.

Short tandem repeat (STR) sequences are used as identity markers. STRs are di-, tri-, or tetra-nucleotide repeat sequences interspersed throughout the genome at specific sites. There is variability in STR length among people and the STR lengths remain stable throughout life, making them useful as identity markers. Polymerase chain reaction is used to amplify selected STR regions from germline DNA of both donor and recipient. The lengths of the amplified fragment are evaluated for differences (informative markers). Following allogeneic hematopoietic cell infusion, the recipient blood or bone marrow can again be evaluated for the informative STR regions to identify chimerism and estimate the proportions of donor and recipient cells in the specimen.

This test evaluates the donor specimen prior to the recipient bone marrow transplant.

Reference Values

An interpretive report will be provided.

Interpretation

An interpretive report will be provided, which includes whether chimerism is detected or not and, if detected, the approximate percentage of donor and recipient cells. Sorted cell analysis permits more detailed evaluation of chimeric status in T-cell and myeloid cell fractions, which can be helpful in clinical management.

It is most useful to observe a trend in chimerism levels. Clinically critical results should be confirmed with 1 or more subsequent specimens.

Cautions

Sensitivity varies with the proportions of donor and recipient cells in the specimen. For this reason, results are reported as approximate and rounded to the nearest 5% or 10%, depending on the calculated percentage of donor cells. For example, if the percent donor is 10% or less, it is reported as 5% donor cells. If the percent donor cells are 90% or higher, it is reported as 95% donor cells. In rare cases (eg, matched related stem cell transplants), short tandem repeat patterns may be identical (ie, noninformative) and chimeric status cannot be determined with this test. Use of alternative approaches (eg, XY fluorescence in situ hybridization in patients with opposite sex transplants) may be required.

Clinical Reference

1. Antin JH, Childs R, Filipovich AH, et al: Establishment of complete and mixed donor chimerism after allogenic lymphohematopoietic transplantation: recommendations from a workshop at the 2001 Tandem Meetings. Biol Blood Marrow Transplant. 2001;7:473-485

2. Tang X, Alatrash G, Ning J, et al: Increasing chimerism following allogeneic stem cell transplantation is associated with longer survivial time. Biol Blood Marrow Transplant. 2014 August;20(8):1139-1144. doi: 10.1016/j.bbmt.2014.04.003

3. Ludeman MJ, Zhong C, Mulero JJ, et al: Developmental validation of GlobalFiler PCR amplification kit: a 6-dye multiplex assay designed for amplification of casework samples. Int J Legal Med. 2018 Nov;132(6):1555-1573. doi: 10.1007/s00414-018-1817-5

4. Tyler J, Kumer L, Fisher C, et al: Personalized chimerism test that uses selection of short tandem repeat or quantitative PCR depending on patient's chimerism status. J Mol Diagn. 2019 May;21(3):483-490. doi: 10.1016/j.jmoldx.2019.01.007

5. Lion T, Watzinger F, Preuner S, et al: The EuroChimerism concept for a standardized approach to chimerism analysis after allogeneic stem cell transplantation. Leukemia. 2012 Aug;26(8):1821-1828. doi: 10.1038/leu.2012.66

Performance

Method Description

Genomic DNA is extracted from blood or bone marrow aspirate samples using an automated extraction platform and used in a commercial GlobalFiler Polymerase chain reaction (PCR) Amplification KIT following the manufacturer's instructions. Briefly, 20 different short tandem repeat (STR) marker regions are amplified in single multiplex PCR using primers labeled with fluorescent tags. The products are analyzed for size and amount using capillary electrophoresis. For the initial sample on any patient, the test is performed on 3 separate DNA samples: donor germline DNA, recipient germline DNA, and recipient posttransplant sample for chimerism determination. The STR profile of the germline samples is used to identify markers that can distinguish between the donor and recipient. Based on these profiles, the percentage of donor and recipient DNA is then determined in the posttransplant sample using the assumptions and calculations outlined in Thiede C et al 1999. Subsequent samples for chimerism evaluation do not need to be accompanied by samples for donor and recipient germline evaluation, as the profiles from the initial testing are kept on file for comparison.

The sensitivity of this analysis is approximately 5% in a post-transplant specimen (donor and recipient DNA mixed chimerism).(Package insert: GlobalFiler PCR Amplification Kit. TheromFisher Scientific; 08/21/2019; Thiede C, Florek M, Bornhauser M, et al: Rapid quantification of mixed chimerism using multiplex amplification of short tandem repeat markers and fluorescence detection. Bone Marrow Transplant. 1999;23:1055-1060)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

4 to 8 days

Specimen Retention Time

Blood/Bone marrow: 2 weeks; Extracted DNA: Indefinitely

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test was developed, and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

81265-Comparative analysis using short tandem repeat (STR) markers; patient and comparative specimen (e.g., pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [e.g., buccal swab or other germline tissue sample] and donor testing, twin zygosity testing or maternal cell contamination of fetal cells)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CHIDB	Chimerism-Donor	31208-2

Result ID	Test Result Name	Result LOINC Value
MP008	Recipient	46106-1
MP015	Specimen Type	31208-2
83182	Chimerism-Donor (CHIDB)	No LOINC Needed