



THXID[®]-BRAF

Test Reference Sheet

FDA-APPROVED CDX FOR BRAF V600E AND V600K MUTATION DETECTION IN MELANOMA (PMA #P120014)

Clinical Significance:

V600E mutations account for 70 to 90% of BRAF mutant melanoma cases¹.
 V600K mutations account for ~6% to 29% of BRAF mutant melanoma cases¹.

Sample type: Formalin-fixed paraffin-embedded (FFPE) human melanoma tissue

Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)

Results Reported from THXID-BRAF¹

REPORTED RESULT	DESCRIPTION
BRAF mutation negative	V600E & V600K mutations not detected
V600E mutation	V600E mutation detected
V600K mutation	V600K mutation detected
V600E & V600K mutations	V600E & V600K mutations detected

**Comparison to cobas[®] 4800 BRAF V600 Mutation Test
 Roche Diagnostics; PMA #P110020**

	FDA-APPROVED DETECTION		SENSITIVITY		LOD (LIMIT OF DETECTION)	
	V600E	V600K	V600E	V600K	V600E	V600K
THXID-BRAF ¹	YES	YES	96.3%	92.2%	5%	5%
cobas [®] 4800 BRAF mutation test ²	YES	NO	97.3%	65.6% ^{nc}	5%	31% ^{nc}

^{nc}Non-Clinical results: The cobas[®] 4800 BRAF V600 Mutation Test does not reliably detect non-V600E mutation, per the cobas[®] 4800 BRAF V600 Mutation Test Package Insert, p 22. cobas 4800 BRAF mutation test is not FDA-approved for detection of BRAF V600K.



THXID[®]-BRAF

HEMATOGENIX LABORATORY SERVICES, LLC	LABORATORY CORPORATION OF AMERICA, INC.	QUEST DIAGNOSTICS, INC.	GENOPTIX, INC.
Test code: BRAF - FDA approved Website: www.hematogenix.com Phone: 888-Hemato-1 708-444-0444 Fax: 708-444-0445 Address: 8150 W 185th St, Suite A Tinley Park, IL 60487 Email: clientservices@hematogenix.com	Test Name: BRAF Gene Mutation Analysis, Melanoma Test Number: 481110 Website: www.labcorp.com Phone: 800-345-4363, CMBP Customer Service Address: 1912 TW Alexander Dr, Research Triangle Park, NC 27709	Test Name: Melanoma, BRAF V600E & V600K Mutation Analysis, THxID Website: www.questdiagnostics.com Phone: 866-697-8378 Address: Nichols Institute, 33608 Ortega Highway, San Juan Capistrano, CA 92675 USA	Test Name: THXID BRAF Mutation Analysis Website: www.genoptix.com Phone: 800-755-1605 Fax: 800-755-1604 Email: clientservices@genoptix.com Address: 2110 Rutherford Rd, Carlsbad, CA 92008 USA

For the most updated list of Laboratories providing THXID-BRAF testing, please visit: www.biomerieux-usa.com/clinical/thxid-braf, and click the "PROVIDING LABORATORIES" tab underneath the horizontal blue bar.

NOTE: Many laboratories offer one or both FDA-approved BRAF tests for melanoma and a lab-developed BRAF test for other pathologies. To ensure that your sample is tested with THXID-BRAF, the FDA-approved test that is approved and sensitive for V600K as well as V600E, request it by including the laboratory and test code and/or by writing on the test requisition: **Please test with THXID[®]-BRAF**

ELIGIBILITY BASED ON THXID-BRAF TEST RESULT			
THXID-BRAF test result	dabrafenib	trametinib	dabrafenib + trametinib
V600E	✓ 3	✓ 4	✓ 5
V600K	✗	✓ 4	✓ 5

¹THXID[®]-BRAF package insert, ²cobas[®] 4800 BRAF mutation test package insert, Doc Rev. 1.0, ³BREAK-3 phase III trial (NCT01227889), ⁴METRIC trial (NCT01245062), ⁵COMBI-d trial (NCT01584648)