



Advanced Diagnostic Laboratories
1400 Jackson Street, Denver, CO 80206
Client Services (p): 800.550.6227 (f): 800.652.9556
ClinRefLabs@njhealth.org njlabs.org
CAP# 2178901 CLIA # 06D0644307

Patient Name: DOE, JOHN
DOB: 6/1/2006 **Age:** 18Y
Gender: M
Medical Record #: MX00001234

Client Name: LIS REFERRAL CLINIC - FOR BILL
Physician: GENERAL, PHYSICIAN
Submitter ID #:
Account #: MX00000000

DOE, JOHN

Order #: 630XXXXXX

Infectious Disease Pharmacokinetics Laboratory

Collected: 11/1/2023 9:03 AM
Received: 11/1/2023 9:06 AM
Date and time of last dose: 11/01/2023 at 0600
Was full dose taken? Yes
Verified: 11/1/2023 9:08 AM

Trikafta Serum Levels

Tezacaftor Result (mcg/mL)	Ivacaftor Result (mcg/mL)	Elexacaftor Result (mcg/mL)
8.8	1.1	9.9

Ideal draw time is 2-4 hours post dose. The manufacture's maximum observed concentrations (Cmax) for patients 12 years or older are included. On average, the time to reach maximum concentration after dosing Tezacaftor (3 hours), Ivacaftor (4 hours), and Elexacaftor (6 hours).

Target	Cmax Range (mcg/mL)
Tezacaftor	6 - 9.4
Ivacaftor	0.9 - 1.5
Elexacaftor	7.1- 11.3

Additional information available online:

Drug interactions : <https://www.trikaftahcp.com/drug-interactions>.

Additional information about Children under 12: <https://www.trikafta.com/study-information#>

NDA/BLA Multi-disciplinary Review and Evaluation: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/212273Orig1s000MultidisciplineR.pdf

TRKAFTA USPI: https://pi.vrtx.com/files/uspi_elexacaftor_tezacaftor_ivacaftor.pdf

Note, if there are consequential questions regarding a patient's dosing, patient sample acquisition at two or three time points may increase the accuracy of test interpretation. For follow up questions, Adx Laboratories can be reached at 800.550.6227.

The performance characteristics for this test have been validated by Advanced Diagnostic Laboratories at National Jewish Health. It has not been cleared or approved by the US Food and Drug Administration. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. This laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) as qualified to perform high complexity clinical laboratory testing.

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DOE, JOHN

Order #: 630XXXXX

HOUSTON, SAMUEL

MRN: MX0001521

Order #: 630100002

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