DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

CLIA ADVERSE ACTION EXTRACT

CMS FORM 462A: HARD COPY TO BE COMPLETED BY THE STATE OR RO:

1. PROVIDER NUMBER *(CLIA ID number)*:

2. LABORATORY NAME AND ADDRESS:

3. FORM ORIGINATION DATE:
M M D D Y Y

4. OWNER(S) *(First Name, Last Name, Middle Initial):*

5. OPERATOR(S) *(First Name, Last Name, Middle Initial):* *

ORIGIN OF ENFORCEMENT ACTION

6. TYPE OF EVENT:

SURVEY DATE:
M M D D Y Y

- ☐ INITIAL SURVEY
- ☐ RECERTIFICATION SURVEY
- ☐ RANDOM SAMPLE VALIDATION SURVEY (For accredited, CLIA exempt, waived laboratories or laboratories holding certificates for physician-performed microscopy procedures)
- ☐ COMPLAINT SURVEY
- ☐ REVISIT
- ☐ UNSUCCESSFUL PARTICIPATION IN PT ..... (DATE REPORTED) M M D D Y Y
- ☐ NON-PAYMENT OF FEE ..... (DATE DUE) M M D D Y Y
- ☐ ACTION BY THE INSPECTOR GENERAL

7. SURVEY RELATED BASIS OR BASES FOR ADVERSE ACTION *(Specify all that apply)*:

- ☐ CONDITION LEVEL NONCOMPLIANCE WHICH DOES NOT POSE IMMEDIATE JEOPARDY
- ☐ IMMEDIATE JEOPARDY (DATE JEOPARDY REMOVED, IF APPLICABLE) M M D D Y Y
- ☐ TESTING WITHOUT THE APPROPRIATE CLIA CERTIFICATE
- ☐ REFUSAL TO COOPERATE WITH SURVEY TEAM'S REQUESTS
- ☐ REFUSAL TO PROVIDE INFORMATION REQUESTED BY CMS OR ITS AGENT
- ☐ LABORATORY OWNER, OPERATOR, OR EMPLOYEE MEETS THE CRITERIA SET FORTH AT §493.1840
- ☐ STANDARD LEVEL NONCOMPLIANCE NOT CORRECTED WITHIN 12 MONTHS OR BY DATE SPECIFIED ON THE PLAN OF CORRECTION

8. DATE(S) OF REVISIT(S):

M M D D Y Y M M D D Y Y M M D D Y Y

* Note: Operators include the Responsible Laboratory Directors.

CLIA ADVERSE ACTION EXTRACT

CMS FORM 462B (ON ODIE ONLY):

9. DATE FINAL NOTICE OF SANCTION SENT TO THE LABORATORY:
(5 days prior to the imposition of the sanction for an immediate jeopardy situation, 15 days prior to the imposition of the sanction for a non-immediate jeopardy situation.)
M M D D Y Y

10. DATE FIRST ADVERSE ACTION IMPOSED:
M M D D Y Y

INDICATE SANCTIONS IMPOSED:

11. INTERMEDIATE SANCTION:

	EFFECTIVE DATE	DATE RESCINDED
1. CIVIL MONEY PENALTY ($_____.____)	M M D D Y Y	M M D D Y Y
Specify: per day $_____.____		
per violation $_____.____		
2. STATE ONSITE MONITORING	M M D D Y Y	M M D D Y Y
3. DIRECTED PLAN OF CORRECTION	M M D D Y Y	M M D D Y Y
4. SUSPENSION OF PART OF MEDICARE/MEDICAID PAYMENTS	M M D D Y Y	M M D D Y Y
5. SUSPENSION OF ALL MEDICARE/MEDICAID PAYMENT	M M D D Y Y	M M D D Y Y

12. PRINCIPAL SANCTION:

1. CANCELLATION OF MEDICARE/MEDICAID APPROVAL *(Check box 'D' if action is due to denial of application for a CLIA certificate)*	M M D D Y Y	M M D D Y Y	D
2. REVOCATION OF CLIA CERTIFICATE *(Check box 'D' if action is due to denial of application for a CLIA certificate)*	M M D D Y Y	M M D D Y Y	D
3. SUSPENSION OF CLIA CERTIFICATE	M M D D Y Y	M M D D Y Y	
4. LIMITATION OF CLIA CERTIFICATE *(Complete ITEM below)*	M M D D Y Y	M M D D Y Y	

SPECIALTIES/SUBSPECIALTIES/ANALYTES WHICH THE LABORATORY IS NOT AUTHORIZED TO TEST, BASED ON THE LIMITATION OF ITS CLIA CERTIFICATE:

SPEC / SUBS / ANALYTE	SPEC / SUBS / ANALYTE	SPEC / SUBS / ANALYTE
SPEC / SUBS / ANALYTE	SPEC / SUBS / ANALYTE	SPEC / SUBS / ANALYTE
SPEC / SUBS / ANALYTE	SPEC / SUBS / ANALYTE	SPEC / SUBS / ANALYTE

13. ADDITIONAL ENFORCEMENT ACTION: TRAINING AND TECHNICAL ASSISTANCE FOR UNSUCCESSFUL PARTICIPATION IN PT:

DATE BEGUN	DATE ENDED
M M D D Y Y	M M D D Y Y

14. DENIAL OF CLIA CERTIFICATION:

M M D D Y Y

15. VOLUNTARY WITHDRAWAL OF TESTING (SPECIFY SPECIALTIES/SUBSPECIALTIES/ANALYTES, AND DATES THAT CMS WAS NOTIFIED OF THE WITHDRAWAL):

SPEC / SUBS / ANALYTE — M M D D Y Y

SPEC / SUBS / ANALYTE — M M D D Y Y

SPEC / SUBS / ANALYTE — M M D D Y Y

SPEC / SUBS / ANALYTE — M M D D Y Y

SPEC / SUBS / ANALYTE — M M D D Y Y

SPEC / SUBS / ANALYTE — M M D D Y Y

16. DATE REQUEST FOR ADMINISTRATIVE APPEAL RECEIVED BY RO:

M M D D Y Y

17. ADMINISTRATIVE APPEAL DECISION:
(Check ONE box:)

HHS DETERMINATION:
Reversed ☐
Sustained ☐
Modified ☐

M M D D Y Y
DATE OF DECISION

18. DATE OF CERTIFICATION OF COMPLIANCE FOR ENTIRE LABORATORY:

M M D D Y Y

19. CIVIL ACTION:
DATE INJUNCTION ISSUED BY U.S. DISTRICT COURT AT THE REQUEST OF CMS

M M D D Y Y

20. DATE APPEAL FILED BY LABORATORY IN U.S. DISTRICT COURT:

M M D D Y Y

21. U.S. DISTRICT COURT OF APPEALS DECISION:
(Check ONE box)

HHS DETERMINATION:
Reversed ☐
Sustained ☐
Modified ☐

M M D D Y Y
DATE OF DECISION

22. DATE APPEAL FILED BY LABORATORY IN U.S. COURT OF APPEALS:

M M D D Y Y

23. U.S. COURT OF APPEALS DECISION:
(Check ONE box)

HHS DETERMINATION:
Reversed ☐
Sustained ☐
Modified ☐

M M D D Y Y
DATE OF DECISION

24. DATE APPEAL FILED BY LABORATORY IN U.S. SUPREME COURT:

M M D D Y Y

25. U.S. SUPREME COURT DECISION:
(Check ONE box)

HHS DETERMINATION:
Reversed ☐
Sustained ☐
Modified ☐

M M D D Y Y
DATE OF DECISION

CLIA ADVERSE ACTION EXTRACT

A. General - The CLIA Adverse Action Extract is primarily intended for use by the State agency (SA) and the Regional Office (RO) to keep a record of the adverse actions imposed against a laboratory for noncompliance with one or more CLIA requirements. The document is divided into two parts: the CMS-462A, which is completed by the State or the RO following a survey and then entered into the CLIA database of OSCAR, and the CMS-462B, which is updated by the RO through the same CLIA database. Information from this form will be used to compile the annual Laboratory Registry, as mandated by §353(n) of the Public Health Service Act, as well as to document enforcement action for billing laboratories under CLIA.

B. Instructions for completing form

1. Enter the laboratory's 10-digit Provider Number (CLIA identification number).
2. Enter the name, address, and telephone number of the laboratory.
3. Identify the date on which this form was initiated.
4. Enter the name(s) of the laboratory's owner(s).
5. Enter the name(s) of the laboratory's operator(s).
6. Specify the event(s) through which noncompliance was identified, inserting dates where indicated. Exclude revisits.
7. Specify each survey-related basis for adverse action.
8. Enter date(s) of revisit(s) by CMS, the SA, or other CMS agent.
9. Enter the date on which the final notice of sanction is sent to the laboratory. In the case of immediate jeopardy, the notice from the RO will be sent to the laboratory via overnight mail at least 5 working days prior to the imposition of a sanction. In the case of noncompliance which does not pose immediate jeopardy, the notice from the RO will be sent to the laboratory at least 15 calendar days prior to the imposition of a sanction.
10. Enter the date the first adverse action is imposed against the laboratory.
11. Specify the sanctions imposed, and the effective date of each. Fill in the amount of civil money penalty, if one is imposed. Where applicable, insert the date each sanction was rescinded. Check the box labelled "D" if a revocation of a laboratory's CLIA certificate and cancellation of approval for the laboratory to receive Medicare and Medicaid payment is due to a denial of a laboratory's application for a CLIA certificate.
12. Indicate the principal sanctions imposed against the laboratory, the effective date of each, and, in the case of a limitation of the laboratory's CLIA certificate, the specialties, subspecialties, or analytes which the laboratory is not authorized to test under its limited CLIA certificate. Where applicable, indicate the date each sanction was rescinded. (Note: the limitation of testing of a CLIA certificate at the analyte level is contingent on appropriate systems capability. The lack of such capability may be offset by the use of voluntary withdrawal from the testing of specific analytes under the directed plan of correction, as may be indicated under item 15.)
13. State whether training and technical assistance for unsuccessful participation in PT is imposed, its effective date, and the date on which the training and technical assistance was completed.
14. If a laboratory's CLIA certificate is denied, fill in the effective date of the denial.
15. Specify if the laboratory has voluntarily withdrawn from testing, and indicate which specialties, subspecialties, or analytes the laboratory has agreed not to test, and the effective date of the voluntary withdrawal of each.
16. Indicate the date a request for an administrative appeal was received by the CMS Regional Office.
17. Indicate the outcome of the administrative appeal, and the date the decision was rendered.
18. Enter the date on which the entire laboratory is certified to be in compliance with all applicable CLIA requirements, if this occurs.
19. Enter the date of the issuance of an injunction by the U.S. District Court against a laboratory.
20. Enter the filing date of an appeal by the laboratory with the U.S. District Court.
21. Indicate the decision of the U.S. District Court, and the date it was rendered.
22. Fill in the date the laboratory filed an appeal in U.S. Court of Appeals.
23. Indicate the decision of the U.S. Court of Appeals.
24. Fill in the date the laboratory filed an appeal in the U.S. Supreme Court.
25. Indicate the decision of the U.S. Supreme Court, and the date it was rendered.