THE MEDICARE CLINICAL LABORATORY COMPETITIVE BIDDING DEMONSTRATION PROJECT APPLICATION FORM

For CMS Use Only

Application Number	Date Application Received

A. BIDDING STATUS

ALL organizations currently supplying, or planning to supply, more than $1,000 in demonstration tests annually are required to complete this application**. Bidders should complete all sections of this application. Non-bidders only need to complete sections A, B (items 1-6, 10,11) and G.** The rules of the demonstration are found in the APPLICATION FORM: INSTRUCTIONS FOR COMPLETION**.** Check either 1 or 2 *and* indicate whether or not you are bidding:

1. ❑ The applicant is required to bid under the rules of the demonstration ***and*** is:
   - ❑ bidding on the demonstration tests
   - ❑ **not** bidding on the demonstration tests (and therefore will not receive Medicare Part B payment for demonstration tests)

2. ❑ The applicant is not required to bid under the rules of the demonstration ***and*** is:
   - ❑ bidding on the demonstration tests
   - ❑ **not** bidding on the demonstration tests (and therefore will receive Medicare Part B payment for demonstration tests)

B. APPLICANT INFORMATION

B1. Business and Ownership Information

1. Applicant's Business Information

Applicant's Legal Business Name		
Mailing Address *(Number, Street)*		
City	State	Zip Code
Telephone Number *(Include Area Code)*	Fax Number *(Include Area Code)*	

Indicate the length of time the applicant completing this form has been doing business in the CBA. _____years, _____months

2. Federal Tax Identification Number (TIN) _____

3. "Doing Business As" Name _____

4. Type of Business

Type of Healthcare Organization

- ❑ Independent Laboratory
- ❑ Hospital
- ❑ Physician Office
- ❑ Outpatient/Ambulatory Surgery Center or Clinic
- ❑ Nursing Home
- ❑ Dialysis Facility
- ❑ Home Health Agency
- ❑ Other (please specify) _____

Type of Ownership

- ❑ Government (local or state)
- ❑ Private non-profit
- ❑ Proprietary, individual
- ❑ Proprietary, partnership
- ❑ Proprietary, corporate (privately held)
- ❑ Proprietary, corporate (publicly traded)
- ❑ Other (please specify) _____

5. Ownership

Read the instructions for completion carefully. List individually each owner, partner, or managing organization of the applicant. If additional space is needed, check here ❑ and attach the additional information using the same format.

Owner #1 Legal Name as Reported to the IRS

Mailing Address *(Number, Street)*

City	State	Zip Code

Telephone Number *(Include Area Code)*	Fax Number *(Include Area Code)*
Federal Tax Identification Number (TIN)	Fiscal Intermediary (FI) Medicare Provider Number (if applicable)

"Doing Business As" Name

Check all that apply and provide the relevant dates and percent ownership where applicable:

❑ 5% or more ownership interest (Effective date of ownership _____ % ownership_____)
❑ Managing Organization (Effective date of control of Managing Organization_____)
❑ Partner (Effective date of partnership _____)

Owner #2 Legal Name as Reported to the IRS

Mailing Address *(Number, Street)*

City	State	Zip Code

Telephone Number *(Include Area Code)*	Fax Number *(Include Area Code)*
Federal Tax Identification Number (TIN)	Fiscal Intermediary (FI) Medicare Provider Number (if applicable)

"Doing Business As" Name

Check all that apply and provide the relevant dates and percent ownership where applicable:

❑ 5% or more ownership interest (Effective date of ownership _____ % ownership_____)
❑ Managing Organization (Effective date of control of Managing Organization_____)
❑ Partner (Effective date of partnership _____)

6. Business Establishment Information

(Current) Establishment/Incorporated
State Date *(mm/dd/yyyy)*

Additional Information

(Historic) Previously Established/Incorporated
State Date *(mm/dd/yyyy)*

Additional Information

B2. Quality and Medicare Information

7. Quality Assurance Contact

Name

Title

Mailing Address

City	State	Zip Code

Telephone Number *(Include Area Code)*	Fax Number *(Include Area Code)*

E-mail Address

8. Laboratory Registry

Have any of the applicant's laboratories ever appeared on the annual Laboratory Registry under CLIA?

❑ YES ❑ NO

If yes, please provide the laboratory name, laboratory director, address, CLIA identification number and date.

If yes, was the CLIA certificate ❑ Suspended ❑ Limited ❑ Revoked ❑ Other

9. Proficiency Testing

Check all programs the applicant's laboratories currently participate in:

❑ Accutest ❑ AAB ❑ CTS ❑ EXCEL ❑ MLE ❑ New Jersey ❑ CAP ❑ AAFP

❑ API ❑ Pennsylvania ❑ Puerto Rico ❑ WSLH ❑ Maryland ❑ ASCP ❑ New York State

May we contact the proficiency testing program(s)? ❑ YES ❑ NO (please explain below)

10. Laboratory(ies) Serving the CBA

If additional space is needed, check here ❑ and attach the additional information using the same format.

Laboratory #1 Legal Business Name

Mailing Address *(Number, Street)*

City	State	Zip Code

Laboratory Director (name)

Does this person direct other laboratories? ❑ YES ❑ NO

If yes, please list the name(s), address(es), and the CLIA Identification Number of the additional laboratory(ies).

Is this a Medicare certified facility? ❑ YES ❑ NO

If yes, please indicate the Fiscal Intermediary (FI) Medicare Provider Number _____

Provider Number Assigned by Medicare Part B Carrier (indicate "n/a" if not applicable)	National Provider Identification (NPI) number
CLIA Identification Number	Hospital or Part A Medicare Provider Number (indicate "n/a" if not applicable)

Indicate the type of CLIA certificate held by the laboratory and the expiration date of the certificate.

❑ Certificate of Compliance _____(expiration date) ❑ Certificate of Accreditation _____(expiration date)

If the laboratory holds a Certificate of Accreditation under CLIA, please indicate the accrediting organization(s).

❑ JCAHO ❑ AOA ❑ AABB ❑ CAP ❑ COLA ❑ ASHI

May we contact the accrediting organization(s)? ❑ YES ❑ NO

Laboratory #2 Legal Business Name

Mailing Address *(Number, Street)*

City	State	Zip Code

Laboratory Director (name)

Does this person direct other laboratories? ❑ YES ❑ NO

If yes, please list the names and addresses of the additional laboratories.

Is this a Medicare certified facility? ❑ YES ❑ NO

If yes, indicate the Fiscal Intermediary (FI) Medicare Provider Number _____

Provider Number Assigned by Medicare Part B Carrier (indicate "n/a" if not applicable)	National Provider Identification (NPI) number
CLIA Identification Number	Hospital or Part A Medicare Provider Number (indicate "n/a" if not applicable)

10. Laboratory (ies) Serving the CBA (continued)

Laboratory #2 (continued)
Indicate the type of CLIA certificate held by the laboratory and the expiration date of the certificate.
❑ Certificate of Compliance _____(expiration date) ❑ Certificate of Accreditation _____(expiration date)

If the laboratory holds a Certificate of Accreditation under CLIA, please indicate the accrediting organization(s).

❑ JCAHO ❑ AOA ❑ AABB ❑ CAP ❑ COLA ❑ ASHI

May we contact the accrediting organization(s)? ❑ YES ❑ NO

Laboratory #3 Legal Business Name

Mailing Address *(Number, Street)*

City	State	Zip Code

Laboratory Director (name)

Does this person direct other laboratories? ❑ YES ❑ NO
If yes, please list the names and addresses of the additional laboratories.

Is this a Medicare certified facility? ❑ YES ❑ NO
If yes, indicate the Fiscal Intermediary (FI) Medicare Provider Number _____

Provider Number Assigned by Medicare Part B Carrier (indicate "n/a" if not applicable)	National Provider Identification (NPI) number
CLIA Identification Number	Hospital or Part A Medicare Provider Number (indicate "n/a" if not applicable)

Indicate the type of CLIA certificate held by the laboratory and the expiration date of the certificate.
❑ Certificate of Compliance _____(expiration date) ❑ Certificate of Accreditation _____(expiration date)

If the laboratory holds a Certificate of Accreditation under CLIA, please indicate the accrediting organization(s).

❑ JCAHO ❑ AOA ❑ AABB ❑ CAP ❑ COLA ❑ ASHI
May we contact the accrediting organization(s)? ❑ YES ❑ NO

B3. Financial and Legal Information

11. Authorized Official(s)

Authorized Official(s) First Name	Last Name	Title
Telephone Number *(Include Area Code)*	E-mail Address	
Authorized Official(s) First Name	Last Name	Title
Telephone Number *(Include Area Code)*	E-mail Address	

12. Bank References

Reference #1 Institution Name		Line of Credit (if any, in dollars)
Account Number(s)	Contact Person	Telephone Number *(Include Area Code)*
Reference #2 Institution Name		Line of Credit (if any, in dollars)
Account Number(s)	Contact Person	Telephone Number *(Include Area Code)*

13. Financial Information

Please submit the financial information requested in the instructions for this question. An authorized official of the applicant should sign below to certify the submitted financial information.

I HEREBY CERTIFY that I have examined the accompanying financial statement and that to the best of my knowledge and belief, it is a true, correct and complete statement prepared from books and records that we have prepared in accordance with the Generally Accepted Accounting Principles.

Authorized Official (Print)	Title	Date

Authorized Official (Signature)

14. Adverse Legal Actions

Have any of the adverse legal actions listed in Table A (see instructions) been imposed against the applicant, any of the applicant's subcontractors or

any of the applicant's owners? If yes, report each adverse legal action, when it occurred, the law enforcement authority/court/administrative body that imposed the action and the resolution. Attach a copy of the adverse legal action documentation(s) and resolution(s).

Is the applicant, any of the applicant's subcontractors or any of the applicant's owners currently the subject of an investigation that could potentially result in imposition of an adverse legal action listed in Table A (see instructions)? If yes, report the circumstances and status of the investigation.

C. GEOGRAPHIC COVERAGE, TEST MENU, AND SUBCONTRACTING

1. Geographic Coverage

Indicate the zip codes that you currently serve within the CBA. If you serve all of the zip codes in a particular county, you may enter the name of the county.

Are there any specific tests provided by the applicant that are not available for all of the zip codes and counties listed above? ❑ YES ❑ NO
If yes, please provide the HCPCS codes for these tests as well as a brief explanation for why they can not be provided to all of the zip codes and counties you serve in the CBA.

Do you plan to expand your service area under the competitive bidding demonstration project? ❑ YES ❑ NO
If yes, indicate the additional zip codes or counties you will serve within the CBA:

2. Specimen Transport and Logistics

Check all that apply

❑ Specimens are collected by client and transported via courier service (e.g., local courier, FedEx)
❑ Applicant provides specimen collection at client location and transports specimen to testing laboratory
❑ Applicant provides specimen pick-up service for routine and STAT collection
❑ Applicant provides specimen collection on-site at laboratory (primary address)
❑ Applicant provides specimen collection sites within the demonstration area (addresses to be listed below)

Provide a copy of your current requisition or test request form. If not available, provide an explanation.

3. Specimen Collection Locations

Location #1 Name

Mailing Address (Street)

City	State	Zip Code

Function (check all that apply)

❑ Only Specimen Drop Off ❑ Venipuncture ❑ Limited Laboratory Testing (please specify) _____

3. Specimen Collection Locations (continued)

Location #2 Name

Mailing Address (Street)

City	State	Zip Code

Function (check all that apply)

❑ Only Specimen Drop Off ❑ Venipuncture ❑ Limited Laboratory Testing (please specify) _____

Location #3 Name

Mailing Address (Street)

City	State	Zip Code

Function (check all that apply)

❑ Only Specimen Drop Off ❑ Venipuncture ❑ Limited Laboratory Testing (please specify) _____

4. Test Menu

Indicate the CLIA specialty(ies) of testing performed in-house.

❑ Histocompatibility ❑ Microbiology ❑ Diagnostic Immunology ❑ Chemistry ❑Hematology
❑ Immunohematology ❑ Pathology ❑ Radiobioassay ❑ Clinical Cytogenetics ❑Other (specify) _____

How will your laboratory provide a comprehensive demonstration test menu (for Medicare beneficiaries) under the Competitive Bidding Demonstration Project? Check all that apply.

❑ Laboratory currently offers demonstration test menu (in-house testing)
❑ Laboratory plans to expand (in-house testing, provide additional information in question 6)
❑ Laboratory currently subcontracts/refers to provide demonstration test menu (provide additional information in question 5)
❑ Laboratory plans to subcontract/refer to provide demonstration test menu (provide additional information in question 5)
❑ Other (explain)

5. Subcontracting/Referred Tests

Do you "send out" or refer laboratory tests to another laboratory, or plan to do so under the demonstration? ❑ YES ❑ NO
If yes, please identify the legal entities you currently or anticipate subcontracting or referring tests to, specify what tests will be subcontracted/referred, and specify the prices charged to the applicant for subcontracted/referred tests.

Subcontractor/Reference Laboratory Legal Name	Demonstration Tests or Specialties to be Subcontracted/Referred	Copies of Subcontractor/Reference Laboratory Prices Attached?		
_____	_____	❑ YES	❑ NO	❑ Pending
_____	_____	❑ YES	❑ NO	❑ Pending
_____	_____	❑ YES	❑ NO	❑ Pending
_____	_____	❑ YES	❑ NO	❑ Pending
_____	_____	❑ YES	❑ NO	❑ Pending
_____	_____	❑ YES	❑ NO	❑ Pending

5. Subcontracting/Referred Tests (continued)

If subcontractor/reference laboratory prices charged to the applicant are not attached or are pending, please explain.
If necessary, attach additional pages to explain subcontractor/reference laboratory relationships, tests, and prices.

6. Expansion

Do you plan to expand if awarded a competitive bid contract? ❑YES ❑ NO If yes, describe your expansion plan:

In what month/year do you anticipate that the added capacity from your expansion plan will become available?_____ (month/year)

D. BID PRICES, VOLUME AND CAPACITY

1. Test Volume

What was the total number of tests provided for residents of this CBA by the applicant during calendar year 2005?

❑ 0-50,000	❑ 50,001-100,000	❑ 100,001 – 250,000	❑ 250,001 – 500,000
❑ 500,001-750,000	❑ 750,001- less than 1 million	❑ 1 million – 5 million	❑ More than 5 million

What percentage was for Medicare beneficiaries?

❑ 0% - 10%	❑ 11%-20%	❑ 21%-30%	❑ 31%-40%	❑ 41%-50%
❑ 51%-60%	❑ 61%-70%	❑ 71%-80%	❑ 81%-90%	❑ 91%-100%

2. Revenue

What was the total revenue collected from tests provided for residents of this CBA by the applicant during calendar year 2005?

❑ $0-$250,000	❑ $250,001 - $500,000	❑ $500,001 - $750,000	❑ $750,001 - less than $1 million
❑ $1 million - less than $3 million	❑ $3 million - less than $6 million	❑ $6 million - $10 million	❑ More than $10 million

What percentage was collected from Medicare?

❑ 0% - 10%	❑ 11%-20%	❑ 21%-30%	❑ 31%-40%	❑ 41%-50%
❑ 51%-60%	❑ 61%-70%	❑ 71%-80%	❑ 81%-90%	❑ 91%-100%

3. Non-patient Test Percentage

If you are a hospital or physician office laboratory (or other organization with patients), what percentage of your total test volume in the CBA is provided to non-patients? For example, if you are a hospital providing 15% of your tests as "outreach" business to persons who are not inpatients or outpatients of your organization, check the 11-20% box.

If you are an independent clinical laboratory, check here❑.

❑ 0% - 10%	❑ 11%-20%	❑ 21%-30%	❑ 31%-40%	❑ 41%-50%
❑ 51%-60%	❑ 61%-70%	❑ 71%-80%	❑ 81%-90%	❑ 91%-100%

4. Medicare Bid Price by HCPCS Code

Provide your Medicare bid price in column D for each HCPCS code.

5. Curr

Indicate … idents of the C…

A HCPCS Code	B HCPCS Test Description	C Test Weight	D Bid Price
36415	Routine venipuncture		
78267	Breath tst attain/anal c-14		
78268	Breath test analysis, c-14		
80048	Basic metabolic panel		
80051	Electrolyte panel		
80053	Comprehen metabolic panel		
80061	Lipid panel		
80061	Lipid panel		
80069	Renal function panel		
80074	Acute hepatitis panel		
80076	Hepatic function panel		

Histoco…

Immun…

Microb…

Patholo…

Diagno…

Radiobioassay

Chemistry

Clinical Cytogenetics

Hematology

Other (specify)_____

Explain any extra capacity you reported above. Check all that apply. Attach additional sheets to explain if necessary.

❑ Extra capacity in current configuration
❑ Expansion plan reported in Section C, question 6
❑ Subcontracting/Referrals
❑ Other (explain) _____

Will all of the extra capacity reported above, if any, be available to provide demonstration tests?
❑ YES ❑ NO (explain)

If necessary, attach additional sheets to explain your capacity to expand demonstration test volume..

E. ADDITIONAL INFORMATION (OPTIONAL)
(Specialized testing services provided, etc.--see instructions)

F. CERTIFYING STATEMENT

I, the undersigned, certify to the following:

1. I have read the contents of this application. By my signature, I certify that the information contained herein is true, correct, and complete.
2. I attest that the applicant will be able to perform the activities in compliance with the terms and conditions of the demonstration.
3. I attest that the applicant agrees to notify CMS in writing of any changes that may jeopardize the applicant's ability to meet the qualifications stated in this application prior to such change or within 15 days of the effective date of such change. If the organization becomes aware that any information in this application is not true, correct, or complete at any time during the application period (or during the contract period if the applicant is awarded a contract), the organization shall notify CMS in writing immediately.
4. I understand that, in accordance with 18 U.S.C. § 1001, any omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or verify this application may be punishable by criminal, civil, or administrative actions including revocation of approval, fines, and/or imprisonment.
5. I certify that I am a representative, officer, chief executive officer, or general partner of the applicant and am authorized to submit and certify an application for the Medicare Clinical Laboratory Competitive Bidding Demonstration Project on behalf of the applicant.

Authorized Official Name (First, Middle, Last)	Title/Position
Signature	Date