DIAGNOSTIC LABORATORY
LOCATION APPLICATION

This is a supplemental application. Please complete a separate application for each facility. If a question does not apply to the facility, state "N/A." Use the Remarks section if you need additional space or attach additional pages as necessary. Your signature is required on page 11.

In addition to the completed application, please provide the following items:

- Copies of the facility's letterhead(s) and advertisements

SECTION I IDENTIFYING INFORMATION

Name of Facility				
Address	City	County	State	Zip Code
Telephone Number	Fax Number	Website Address		

Location Type:
☐ Freestanding – Hospital Satellite ☐ Freestanding – Independent ☐ Hospital-based
☐ Physician's Office
☐ Mobile Unit (specify area of operation): ______________________________
☐ Other (specify): ______________________________

Specialty Type(s):

☐ Chemistry	☐ Clinical Cytogenetics	☐ Diagnostic Immunology
☐ Hematology	☐ Histocompatibility	☐ Immunohematology
☐ Microbiology	☐ Pathology – Cytology	☐ Pathology – Histopathology
☐ Pathology – Ocular	☐ Pathology – Oral	☐ Pathology – Other
☐ Radiobioassay	☐ Other (specify): ______________________________	

Hours of Operation:	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

1. Please describe the ownership of the facility. If there is more than one owner, attach an organizational chart that identifies the facility's ownership structure and each owner's percentage of ownership interest:

____

____

2. Are the services provided in the facility limited to a specific physician or medical group? ☐ **Yes** ☐ **No**

If yes, please identify the physician or medical group:

____

____

SECTION II COVERAGE/INSURANCE INFORMATION

Facility Requested Effective Date (the date you wish coverage to begin)

NOTE: Please complete this question only if this is an application to add a new location to an existing NORCAL policy. NORCAL should receive the application at least thirty days before the Requested Effective Date.

____ 12:01 a.m. Local Time
Month Day Year

Facility Prior Acts Coverage (check one)

If approved, Prior Acts Coverage, also known as Retroactive Coverage or Nose Coverage, would provide protection for claims that 1) are first reported to NORCAL after the Policy Effective Date with NORCAL and the effective date of coverage for this location and 2) arose out of acts or omissions occurring on or after the Policy and location Retroactive Dates and before the termination or Expiration Date of that policy and location. The Retroactive Date is the earliest date on which a medical incident or occurrence may occur and for which coverage may be afforded under the NORCAL policy. Prior Acts Coverage provides an alternative to purchasing Tail Coverage from your current carrier, if applicable. This coverage does not apply to the optional Health Care General Liability Insurance. **NORCAL does not automatically provide Prior Acts Coverage.**

☐ The facility wishes to apply for Prior Acts Coverage. Additional premium will be charged if this coverage is approved. Unless you are notified by NORCAL that your request for Prior Acts Coverage has been approved, do not forfeit your right to purchase Tail Coverage from your current carrier. (Please identify the Requested Retroactive Date below and complete the Prior Acts Coverage section on page 10):

☐ The facility does **not** wish to apply for Prior Acts Coverage. It is understood that if the facility does not obtain Prior Acts Coverage, it will have no coverage with NORCAL for claims arising from any acts or omissions that occurred prior to the effective date of coverage for this location.

Facility Requested Retroactive Date

____ 12:01 a.m. Local Time
Month Day Year

NOTE: The Retroactive Date, if specified, must be the same as the Retroactive Date of your current policy.

Facility Professional Liability Insurance History

NOTE: Please complete the questions in this section only if one of the following applies:

- This is an application to add a new location to an existing NORCAL policy and it is not a brand new facility, or
- The facility's professional liability insurance history is different from the organization's professional liability insurance history as indicated on the Health Care Facilities Policy Application

1. Please complete the following regarding all professional liability insurance maintained by the facility during the past ten years, beginning with the most current. Please photocopy this page if additional space is needed.

Name of Insurer	**Coverage Dates** (month/day/year)	**Deductible or Self-insured Retention?**	**Policy Type**	**If Claims Made, Check One**
	From: To:	☐ **Yes** ☐ **No** If yes, specify type: ________________________ Amount: $______________	☐ Claims Made ☐ Occurrence ☐ Other: _______________	☐ Tail Coverage purchased ☐ Prior Acts Coverage purchased from subsequent insurer ☐ Other: __________________
	From: To:	☐ **Yes** ☐ **No** If yes, specify type: ________________________ Amount: $______________	☐ Claims Made ☐ Occurrence ☐ Other: _______________	☐ Tail Coverage purchased ☐ Prior Acts Coverage purchased from subsequent insurer ☐ Other: __________________

2. If any one of the insurance coverages identified above was Claims Made Coverage, and the group/organization did not purchase Tail Coverage *or* Prior Acts Coverage, please explain in the Remarks section on page 10.

SECTION III HEALTH CARE PROVIDERS

1. Please provide the laboratory director's curriculum vitae.

2. Please identify the number of individuals in the following categories who provide services in or on behalf of the facility.

Provider Type	**Partner/ Shareholder**	**Employee**	**Independent Contractor**	**Staff Member** (excluding those in other categories)	**Other:** ___________ _________________
Physician/Surgeon					
Dentist and Oral and Maxillofacial Surgeon					
Nurse Practitioner					
Physician Assistant					
Cytotechnologist					
Embryologist					
Laboratory Bioanalyst					
Laboratory Technician/Technologist					
Registered Nurse					
Other: ___________________					
Other: ___________________					

3. Does the facility lease any health care personnel from other organizations or individuals (e.g., temporary employment agencies)? ☐ **Yes** ☐ **No**

   If yes, please provide a copy of the contract(s).

4. Are all personnel who provide professional health care services in or on behalf of the facility licensed and/or certified as required by state law for the services they provide? ☐ **Yes** ☐ **No**

   If no, please explain:

   ____

   ____

5. Please answer the following regarding those individuals who render services in or on behalf of the facility but who are **not** employees:

   a. Are they required to maintain professional liability insurance with limits of liability of at least $1 million per claim/$3 million annual aggregate? ☐ **Yes** ☐ **No**

   b. Are they required to provide proof of professional liability insurance at least annually? ☐ **Yes** ☐ **No**

   If you answered no to question 5a or 5b, please explain:

   ____

   ____

6. Please check all that apply to individuals who are rendering services in or on behalf of the facility but who are not owners or employees:

Share in the facility's profits and/or overhead expenses?	☐ **Yes** ☐ **No**
Use the facility's letterhead?	☐ **Yes** ☐ **No**
Use the facility's advertisements?	☐ **Yes** ☐ **No**
Bill under the facility's name?	☐ **Yes** ☐ **No**

If you answered yes to any one of the above, please identify the name and designation of each individual and the applicable common action(s) pertinent to him or her:

____

____

SECTION IV ACCREDITATION, CERTIFICATION AND LICENSURE

1. Has the facility ever been denied accreditation, certification and/or licensure or has its accreditation, certification and/or licensure ever been suspended or revoked? ☐ **Yes** ☐ **No**

   If yes, please explain and provide a copy of the results of the inspection(s) that led to the denial, suspension or revocation:

   ____

   ____

2. Please provide copies of the facility's state license(s) and CLIA certificate.

   If the facility is not currently licensed and/or CLIA certified, please explain:

   ____

   ____

3. Is the facility currently accredited? ☐ **Yes** ☐ **No**

   If yes, please identify each agency, provide proof of accreditation, a copy of the agency's most recent inspection report and the facility's responses to any contingencies and/or deficiencies:

   ☐ CAP (specify types): ____ ☐ COLA ☐ JCAHO
   ☐ Other: ____

   If no, please indicate the following below:

   - Whether the facility is scheduled for an inspection, and so, specify with which agency and the date of the inspection
   - The agency (governmental or nongovernmental) that last performed an on-site inspection at the facility and the date it performed the inspection:

   ____

   ____

SECTION V LABORATORY SERVICES

1. Please complete the following table regarding the *estimated* number of test systems, assays and examinations to be performed in the facility during the current year and the *actual* number of each performed in the facility during the applicable prior years. The categories are based on the FDA's CLIA categorization criteria. Please provide the numbers for each calendar year (January through December).

Current Year Estimate	**First Prior Year**	**Second Prior Year**	**Third Prior Year**	**Fourth Prior Year**	**Fifth Prior Year**

2. Does the facility comply with the Federal Code of Regulations and state regulations applicable to laboratories as they relate to slide retention, the number of slides permitted to be examined in a day, qualifications of personnel, etc? ☐ **Yes** ☐ **No**

   If no, please explain:
   ____
   ____

3. Are the laboratory services provided in the facility limited to those authorized by its CLIA certification? ☐ **Yes** ☐ **No**

   If no, please explain:
   ____
   ____

4. Are all laboratory tests or examinations classified as "waived" under CLIA performed in conformity with the manufacturer's instructions? ☐ **Yes** ☐ **No**

   If no, please explain:
   ____
   ____

5. Do facility personnel examine specimens collected in or sent from a state that is different from the state in which your facility is located or from a country other than the United States? ☐ **Yes** ☐ **No**

   If yes, please identify the state(s) and/or country(ies), the type(s) of facility(ies) from which they are sent, the type(s) of specimens and tests performed and how often this occurs:
   ____
   ____

6. Does the facility process, test, store or distribute whole blood or blood components? ☐ **Yes** ☐ **No**

   If yes, please describe the services provided:
   ____
   ____

7. Does the laboratory provide the following?

   Andrology Services ☐ **Yes** ☐ **No** **If yes,** percentage of laboratory services devoted to this: _____%
   Embryology Services ☐ **Yes** ☐ **No** **If yes,** percentage of laboratory services devoted to this: _____%

   a. If you indicated that andrology services are provided in the laboratory, please identify the services provided:

      ☐ Semen Analysis ☐ Semen Cryopreservation ☐ Sperm Function Assays ☐ Sperm Processing
      ☐ Other (specify): ____

   b. If you indicated that embryology services are provided in the laboratory, please identify the services provided:

      ☐ Assisted Hatching ☐ Embryo Transfer ☐ Embryo Cryopreservation ☐ Oocyte Cryopreservation ☐ Sperm Injection
      ☐ Other (specify): ____

SECTION VI TELEMEDICINE

Telemedicine is defined as "the practice of health care delivery, diagnosis, consultation, treatment, transfer of medical data and education using interactive audio, video or data communications. Neither a telephone conversation nor an electronic mail message between a licensed health care practitioner and another licensed health care practitioner and/or between a licensed health care practitioner and a patient constitute telemedicine."

1. Does the facility:

   a. Provide telemedicine services? ☐ **Yes** ☐ **No**

   b. Receive telemedicine services? ☐ **Yes** ☐ **No**

   If you answered yes to either of the above, please explain and provide a copy of the contract(s):

   ____

   ____

SECTION VII MISCELLANEOUS

1. Are any drugs, pharmaceuticals, devices or equipment used, administered, distributed or prescribed in or on behalf of the facility that are disapproved or not yet approved by the United States Food and Drug Administration (FDA) for treatment of human beings? ☐ **Yes** ☐ **No**

   If yes, please explain:

   ____

   ____

2. Are all medications stored in a secure location and handled in compliance with federal, state and local laws and regulations? ☐ **Yes** ☐ **No**

3. Is there an emergency power source available? ☐ **Yes** ☐ **No**

4. Does the facility comply with all federal, state and local laws and regulations regarding the disposal of hazardous waste material? ☐ **Yes** ☐ **No**

5. Is all facility equipment maintained, tested and inspected according to manufacturers' guidelines and federal, state and local laws and regulations? ☐ **Yes** ☐ **No**

If you answered no to any one of questions 2 – 5, please explain:

____

____

6. Is the facility involved in any teaching program or is it utilized to train individuals other than employees? ☐ **Yes** ☐ **No**

   If yes, please describe the program, identify who provides the training, who is trained, what type of training is provided and how often this occurs, and attach any applicable information regarding the program:

   ____

   ____

7. Are services of the facility provided under any contractual agreement(s) (excluding those with managed care organizations)? ☐ **Yes** ☐ **No**

   If yes, please identify the organization(s) and person(s) with which it contracts and provide a copy of the contract(s):

   ____

   ____

8. Are the services provided on behalf of the facility limited to those that are usual and customary to laboratories? ☐ **Yes** ☐ **No**

   If no, please explain:

   ____

   ____

9. Are there any changes planned for the facility (for example, new services)? ☐ **Yes** ☐ **No**

If yes, please identify the changes and the anticipated date on which the changes will be made:

____

____

SECTION VIII RISK MANAGEMENT

1. Does the facility have a formal risk management program? ☐ **Yes** ☐ **No**

   a. **If yes,** who (name and title) is responsible for the risk management program?

   ____

   b. **If no,** please explain:

   ____

   ____

Credentialing

1. Does the facility have a formal process to credential its health care providers? ☐ **Yes** ☐ **No**

   a. **If yes,** please identify who performs the initial credentialing (e.g., employee, hospital, outside company):

   ____

   ____

   b. **If no,** please explain:

   ____

   ____

2. Does the facility evaluate the following when credentialing its health care providers?

Claim History	☐ **Yes**	☐ **No**	**If yes,** source(s) used: ______________________
Hospital Privileges	☐ **Yes**	☐ **No**	
Employment History	☐ **Yes**	☐ **No**	**If yes,** source(s) used: ______________________
Education History	☐ **Yes**	☐ **No**	**If yes,** source(s) used: ______________________
Felony/Misdemeanor History	☐ **Yes**	☐ **No**	**If yes,** source(s) used: ______________________
Medical/Dental/Nursing and Narcotic Licenses	☐ **Yes**	☐ **No**	**If yes,** source(s) used: ______________________

If you answered no to any one of the above, please explain:

____

____

3. Does the facility use the same credentialing procedures to credential independent contractors and locum tenens health care providers? ☐ **Yes** ☐ **No**

If no, please describe the credentialing process used:

____

____

4. How often are the facility's health care providers recredentialed?

____

____

Quality Assurance

1. Please identify which of the following written policies and procedures have been established by the facility:

   ☐ Procedures for the collection, processing and examination of specimens based on current standards of practice
   ☐ Responsibilities and duties of all health care providers engaged in the performance of laboratory testing, including the required supervision
   ☐ Accurate descriptions and instructions for all analytic methods and procedures to be performed in the laboratory

   If the facility does not have written policies and procedures for any one of the above, please explain:

   ____

   ____

2. Is the laboratory director's approval required for any new or revised policies and procedures? ☐ **Yes** ☐ **No**

3. How often does the laboratory director review the facility's policies and procedures for possible updates? ____________________

4. Please identify which of the following are included in the facility's quality assurance program (please check all that apply):

   ☐ Preventative maintenance
   ☐ Testing for proper operation of the equipment
   ☐ Periodic direct observation of routine test performance
   ☐ Periodic testing of previously analyzed specimens

5. Does the facility have a formal process to evaluate and address concerns of unexpected outcomes? ☐ **Yes** ☐ **No**

Records

1. Does the facility currently use electronic medical records? ☐ **Yes** ☐ **No**

   If yes:

   a. Who is the vendor? ____

   b. How often are the electronic files backed up? ____

   c. Who backs up the files? ____

   d. Are the backed-up files stored at an off-site location? ☐ **Yes** ☐ **No**

   If you answered no to question 1d, please explain:

   ____

   ____

   e. Are all systems (e.g., inpatient, outpatient, billing, scheduling) electronic? ☐ **Yes** ☐ **No**

   If you answered no to question 1e, how are the different systems coordinated?

   ____

   ____

2. How are record-keeping deficiencies identified and handled?

   ____

   ____

SECTION IX SUPPLEMENTAL QUESTIONS

If you answer YES to any one of the following questions, you must provide a detailed, written narrative (including, but not limited to, date of occurrence, reason for occurrence and the resolution) and pertinent documentation (e.g., medical board documents, letters from a hospital, diversion program and/or treating physician, etc.).

1. Has any governmental agency **ever** investigated, placed on probation, suspended or taken any action against the facility? ☐ **Yes** ☐ **No**
2. Have the facility's membership, contractual participation or employment by any medical organization (e.g., hospital medical staff, group, independent practice association (IPA), health plan, health maintenance organization (HMO), preferred provider organization (PPO), private payer (including those that contract with public programs), medical society, professional association, medical school faculty position or other health delivery entity or system), **ever** been denied, restricted, suspended, revoked, not renewed, voluntarily or involuntarily surrendered, subject to probationary terms or conditions, or otherwise investigated or limited in any way, for possible incompetence, improper professional conduct or breach of conduct, or is any such action pending? ☐ **Yes** ☐ **No**
3. Has the facility **ever** surrendered, allowed to expire, voluntarily or involuntarily withdrawn a request for membership, terminated contractual participation or employment, or resigned from any medical organization (e.g., hospital medical staff, group, independent practice association (IPA), health plan, health maintenance organization (HMO), preferred provider organization (PPO), private payer (including those that contract with public programs), medical society, professional association, medical school faculty position or other health delivery entity or system) while under investigation for possible incompetence or improper professional conduct, or breach of contract, or in return for such an investigation not being conducted, or is any such action pending? ☐ **Yes** ☐ **No**
4. Has the facility or any facility member **ever** been accused of sexual misconduct? ☐ **Yes** ☐ **No**
5. Do you know if any individual who works on the facility's behalf has a prior history or propensity for sexual misconduct? ☐ **Yes** ☐ **No**

SECTION X CLAIMS HISTORY

Other than any claims, incidents, etc. that have already been reported on the organization's main application, if applicable:

1. Within the past ten (10) years, has a malpractice claim or suit been brought against the facility, or has the facility been notified of its involvement in a malpractice claim or suit, either directly or indirectly? ☐ **Yes** ☐ **No**

2. Is the facility aware of any medical incident or accident, conduct, circumstance or occurrence that might reasonably be expected to give rise to a claim or suit against the facility, directly or indirectly, even if you believe the claim or suit would be without merit?
   ☐ **Yes** ☐ **No**

   If you answered yes to question 1 or 2, please complete a Claim Information Form on page 11 for each applicable claim, suit, incident, conduct, etc.

SECTION XI PRIOR ACTS COVERAGE

NOTE: If the facility is not applying for Prior Acts Coverage, please skip this section.

Please ensure that your answers to the following questions reflect the facility's practice as it was during the Prior Acts Period.

1. Since the Requested Retroactive Date, has there been a change in the legal structure of the facility (for example, change in owners, type of entity)? ☐ **Yes** ☐ **No**

   If yes, please explain and identify the appropriate dates:

2. Since the Requested Retroactive Date, have there been any material changes in the facility's practice (for example, types of procedures performed or services provided)? ☐ **Yes** ☐ **No**

   If yes, please explain and identify the appropriate dates:

REMARKS

Beneath "Question Number," please indicate the question number and, if applicable, the letter (e.g., 2, 3b). Please photocopy this page if additional space is needed.

Page Number	Section Number	Question Number	Remarks

Please provide any additional information material to the risk that has not otherwise been addressed in this application:

FOR CALIFORNIA AND RHODE ISLAND FACILITIES ONLY

I represent and warrant the truth of my statements and information mentioned herein, and that I have not withheld any information that may be relevant to the facility's coverage. I agree to notify NORCAL Mutual Insurance Company immediately if the facility's practice changes in any way and of any change in the information contained on this application.

____________________________________ __________________
Signature of Authorized Representative Date

____
Print Name

FOR ALASKA FACILITIES ONLY

I represent the truth of my statements and information mentioned herein, and that I have not withheld any information that may be relevant to the facility's coverage. I agree to notify NORCAL Mutual Insurance Company immediately if the facility's practice changes in any way and of any change in the information contained on this application.

____________________________________ __________________
Signature of Authorized Representative Date

____
Print Name

CLAIM INFORMATION FORM

Name of Patient: ____ Gender: ☐ Male ☐ Female

Age of Patient (at time of treatment): ____

Name of Claimant (if different than patient): ____

Location of Incident: ____

Allegation Against the Facility: ____

____

Facility Member Defendants: ____

____

Non-Facility Member Defendants: ____

____

Date Incident or Claim Was Reported to the Insurance Company: ____

Name of Insurance Company: ____

Disposition or Current Status of the Incident, Claim or Suit Against the Facility:

☐ Open

- ☐ Incident has been reported but claim or suit has not been filed
- ☐ Claim or suit has been filed and is awaiting start of arbitration, mediation, trial, etc.
- ☐ Claim or suit is currently in arbitration or mediation or is being tried in court
- ☐ Settlement has been made or judgment returned but remains open

☐ Closed Date Closed (month/day/year): _____________

- ☐ Incident was reported but claim or suit was not filed
- ☐ Claim or suit was filed but was dismissed or dropped before trial
- ☐ Claim or suit was filed but settlement was made
- ☐ Verdict or judgment was made in the entity's favor
- ☐ Verdict or judgment was made in favor of the plaintiff

Total loss payment amount (if payment made): ___________

Amount paid on the facility's behalf: ___________

Total verdict amount (if different than total loss payment amount): __________

CLAIM INFORMATION NARRATIVE

Please describe the care and treatment of the patient. Attach additional pages as needed. Your narrative must provide adequate clinical detail to allow proper evaluation by a committee of physicians and must include the following information:

- Condition and diagnosis at time of treatment
- Dates and a description of treatment rendered
- Condition of patient subsequent to treatment
- Copies of patient(s) chart(s) and operative report(s) as appropriate

I understand the information submitted herein becomes part of my facility's insurance application as submitted.

Signature of Authorized Representative

Date

Name (Print)