

Application Review Criteria

Part 1: Administration and Personnel

Question 1: Summary Statement.	
	Statement of Laboratory's scope, purpose and mission is provided. Stated purpose indicates that the Laboratory is involved in clinical work.
Que	estion 2: Lab Personnel/Titles/Credentials/Licensure.
	Completed Table of Laboratory personnel included in application.
	Appendix A is included – current CPR or BLS certificates of all staff with direct patient contact provided.
	Appendix B is included – current licensure verifications of all medical /clinical staff provided.
	Laboratory demonstrates that clinical assessments and evaluation are being conducted by or under the supervision of a clinician with credentials/licensure which includes assessment/evaluation within the scope of practice for the population being served.
	Laboratory demonstrates that any invasive procedures performed (including but not limited to fine wire placement) are being conducted by or under supervision of a clinician whose licensure/credentials include such procedures within the scope of their clinical practice.
	The Laboratory demonstrates that data interpretation team includes at least one licensed clinician with demonstrated knowledge and expertise for treatment of conditions present in the population being served.
	The Laboratory demonstrates that personnel involved in clinical recommendations have appropriate licensure.
Que	estion 3: Components of Clinical Evaluation
	The application indicates that the Laboratory captures & reports 3-D kinematics
	The application indicates that the Laboratory captures & reports 3 orthogonal components of force (kinetics)
	The application indicates that the Laboratory measures & reports electromyographic muscle activity (EMG)
	The application indicates that the Laboratory captures all components (kinematics, kinetics, & EMG) simultaneously.



	Documentation of volume of clinical cases provided.
	Documentation of diagnosis categories & percentages of clinical cases provided.
	Documentation of referral process for clinical cases provided.
	Evidence provided that clinical motion studies are performed following physician referral.
	Appendix C is included – Laboratory Referral Form.
Que	estion 4: Consumer Feedback
	Documentation of a mechanism for patient/family satisfaction
	Documentation of a mechanism for referral source satisfaction
	Appendix D included - Surveys
Question 5: Procedure Manuals, Quality Assurance, and Competency	
	Documentation of procedure manual, procedure protocols or operational definitions for physical examination or assessment as performed in the Motion Laboratory. Appendix E is included
	Documentation of a procedure manual or procedure protocol for marker/target placement. Appendix F is included.
	Documentation of a procedure manual or procedure protocol for EMG surface electrode placement as performed in the Motion Laboratory. Appendix G is included.
	Documentation of a procedure manual or procedure protocol for EMG fine wire placement as performed in the Motion Laboratory. Appendix H is included.
	Documentation of a procedure manual or procedure protocol for data collection. Appendix I included.
	Documentation of a procedure manual or procedure protocol for data reduction which includes an established verification system for target tracking and event identification. Appendix J is included.
	Documentation of a process for data interpretation.
П	Documentation of a process for clinical recommendations



Documentation of Quality Assurance Programs in at least two of the following areas within the past 3 years
a. physical exam b. marker/target placement c. surface EMG placement d. fine wire EMG placement e. data collection f. data reduction
Documentation of methods to maintain consistency within personnel for each of the following areas:
a. physical exam b. marker/target placement c. surface EMG placement d. fine wire EMG placement e. data collection f. data reduction g. data interpretation h. clinical recommendations
Documentation of methods to maintain consistency between personnel for each of the following areas:
a. physical exam b. marker/target placement c. surface EMG placement d. fine wire EMG placement e. data collection f. data reduction g. data interpretation h. clinical recommendations
Documentation of methods to achieve initial competency of personnel for each of the following areas is provided:
a. physical exam b. marker/target placement c. surface EMG placement d. fine wire EMG placement e. data collection f. data reduction g. data interpretation h. clinical recommendations



	Documentation of methods to maintain competency of personnel for each of the following areas is provided:
	a. physical exam b. marker/target placement c. surface EMG placement d. fine wire EMG placement e. data collection f. data reduction g. data interpretation h. clinical recommendations
Que	estion 6: Safety Policies and Personnel Competencies
	Documentation of Written Policies for adherence to:
	 Local Building Safety Codes. Appendix K is included. Hazards Communication Program, including Material Safety Data Sheets available for potentially hazardous materials in work area. Appendix L included. Emergency Medical Provision & First Aid Procedures. Appendix M included. Age-Specific Patient Care Services Program for all personnel with direct patient contact (technical and clinical). Appendix N included. Hospital and Departmental Infection Control Policies. Appendix O included.
	Evidence of maintained competency for all personnel by annual training in the following areas. Appendix P included:
	 □ Local Building Safety Codes □ Environmental Safety Procedures □ Emergency Medical Provision & First Aid Procedures (demonstration of current CPR or BLS certification will suffice – see Appendix A) □ Age-Specific Patient Care Services □ Infection Control Procedures
Que	estion 7: Other Accrediting Agencies
	Documentation of current accreditation (including date of expiration) from agencies indicated. Appendix Q included.



Part 2: Equipment **Question 1: Physical Layout** Dimensions and description of current physical space or layout is provided. Appendix R is included. **Question 2: Hardware** Documentation of descriptions for all equipment in current use for routine data collection as described in Part 1 Question 3a. Capability to capture & report 3-D kinematics Capability to capture & report 3 orthogonal components of force (kinetics) Capability to measure & report electromyographic muscle activity (EMG) Evidence of system components for synchronization between kinematic, kinetic, and EMG measurement systems Question 3: Calibration Procedures, Accuracy & Precision: Motion Capture System Documentation of calibration procedures for the motion capture system. Evidence that calibration occurs in accordance with manufacturer's recommendations for the motion capture system being used. Documentation of methods to ensure accuracy (validity) of the motion capture system. Documentation of methods to ensure precision (repeatability) of the motion capture system Appendix S is included. Physical layout in Question 1 is consistent with the calibration volume described in Question 3. Question 4: Calibration Procedures, Accuracy & Precision: Other Systems Documentation that calibration procedures are in place for all additional measurement equipment used for clinical analysis. 1. Force platform system

3. All additional measurement systems as described in Part1 Question 3a.

2. EMG system



Ш	Evidence that calibration occurs in accordance with manufacturer's recommendations for each additional measurement system
	 1. Force platform system 2. EMG system 3. All additional measurement systems as described in Part1 Question 3a.
	Documentation of methods to ensure accuracy (validity) for each additional measurement system
	 1. Force platform system 2. EMG system 3. All additional measurement systems as described in Part1 Question 3a.
	Documentation of methods to ensure precision (repeatability) for each additional measurement system
	 1. Force platform system 2. EMG system 3. All additional measurement systems as described in Part 1 Question 3a.
	Appendix T is included.
Qu	estion 5: Biomechanical Model/Marker Set.
	Evidence that marker set can characterize 3D kinematics of the lower limbs.
	Evidence that the biomechanical model can utilize coordinate trajectories and ground reaction forces to calculate 3D kinetics of the lower limbs.
	Description provided demonstrates that authors understand the strengths and weaknesses of the biomechanical model they are using
	Description provided demonstrates that authors understand the potential sources of error in their calculations.
Pa	rt 3: Data Processing/Data Management/ Reporting
Qu	estion 1: Software/Data Processing/Data Reduction.
	Description of kinematic & kinetic data reduction software provided
	Description of EMG data reduction software provided.
	Description of how processing errors are identified and corrected is provided.



	Description of how gait events are identified is provided.
	Description provided demonstrates that authors understand the strengths and weaknesses of the data reduction software they are using for reduction of kinematic and kinetic data.
	Description provided demonstrates that authors understand the strengths and weaknesses of the data reduction software they are using for reduction of EMG data.
Qu	testion 2. Control Dataset.
	Description of control kinematic and kinetic dataset complete.
	 ☐ Facility & Date(s) of data collection provided. ☐ Description of marker set provided. ☐ Type and Model of motion capture system provided ☐ Type and Model of force plate system provided
	Description of control EMG dataset complete (including facility & date of data collection)
	Suggested table provided and complete with data as requested.
	Description of data averaging, number of gait cycles per patient, and assignment of standard deviation provided.
	If control data taken from the literature or manufacturer, description of methodology for verification of consistency and validity of data with current clinical system is provided.
	Documentation of control kinematic and kinetic data provided. Appendix U included.
	Documentation of control EMG data provided. Appendix V included.
	Documentation of control temporal-distance parameters provided. Appendix W is included if necessary.
Qu	estion 3. Submission of Data Set and Descriptive Clinical Report.
	Data set includes a physical examination relevant to the condition being evaluated
	 ☐ Passive Range of Motion Examination ☐ Lower Extremity Alignment (Transverse/Coronal Plane) ☐ Muscle Testing of Relevant Muscle Groups ☐ Assessment of Selective Motor Control



Comprehensive kinematic data set provided
Conditions of Testing Identified (e.g. barefoot, orthotic, prosthetic, shoes, assistive device, etc.) Clear Identification of Right/Left sides Clear Identification of Gait Cycle Clear Identification of Y-axis label Anatomic/Planar Orientation of Plots Normative Data Included on Plots and Clearly Identified Temporal-Distance parameters included Type of Depicted data clearly identified (representative trial, multiple trials, mean of multiple trials, etc.)
Comprehensive kinetic data set provided
Conditions of Testing Identified (e.g. barefoot, orthotic, prosthetic, shoes, assistive device, etc.) Clear Identification of Right/Left sides Clear Identification of Gait Cycle Clear Identification of Y-axis label Anatomic/Planar Orientation of Plots Normative Data Included on Plots and Clearly Identified
Comprehensive EMG data set provided
 ☐ Clear Identification of Right/Left sides ☐ Clear Identification of Gait Cycle ☐ Normative Data Included on Plots and Clearly Identified ☐ Clear Identification of Type of processing, if appropriate ☐ Muscles or Muscle Abbreviations clearly identified
Comprehensive Clinical History data set provided
☐ Identification of chief complaint or reason for study ☐ Documentation of pertinent past medical history ☐ Documentation of pertinent past surgical history ☐ Documentation of current orthotic, prosthetic, assistive device use



	Comprehensive Clinical/Interpretive Report provided Anatomic and/or Problem List Organization of Report Identification of Clinically Important Deviations/Abnormalities Identification of Possible Specific Treatment Options Based on Deviations/Abnormalities Names, profession, signatures of interpreters included. At least one of interpreters has a medical practice license.
	The Laboratory demonstrates that treatment recommendations (including appropriate referrals) are made consistent with the clinician's licensure guidelines.
Que	estion 4. Data Management/Confidentiality
	Documentation of data management for raw data provided Location Back-Up Security Confidentiality Duration
	Documentation of data management for processed data provided Location Back-Up Security Confidentiality Duration
	Documentation of data management for video data provided Location Back-Up Security Confidentiality Duration
	Documentation of data management for clinical history/questionnaires provided Location Back-Up Security Confidentiality Duration
	Documentation of data management for physical examination provided Location Back-Up Security Confidentiality Duration



Documentation of data management for clinical files provided
Location Back-Up Security Confidentiality Duration
Documentation of Written Policies regarding back-up procedures, security measures, and patient confidentiality in the following area. Appendix Y included and complete.
 ☐ Information Systems. ☐ Protected Health Information ☐ Medical Records or Health Information Systems
Evidence of maintained competency for all personnel by annual training in the following areas. Appendix Z included:
 ☐ Information Systems. ☐ Protected Health Information ☐ Medical Records or Health Information Systems