Aspireirb
A WIRB-Copernicus Group Company

11491 Woodside Avenue
Santee, CA 92071
619.469.0108
f/ 619.469.4108
www.aspire-irb.com

STUDY APPROVAL NOTIFICATION

Plan for Testing Fingerstick Bloods on Magellan Systems

Sponsor:	**Magellan Diagnostics, Inc.**
Protocol Number:	**276** **July 12, 2017**

The new study listed above was reviewed and approved through expedited review on **July 21, 2017** by **Robert B. Daigneault, MD**, Aspire IRB Board Member. In addition, the **LeadCare® II Blood Lead Analyzer User's Guide, Revision 07** was reviewed.

This study was approved at that time with the following conditions:

- **Informed Consent revised for readability and clarity purposes and to ensure all applicable required elements of consent are satisfied.**

The above-referenced conditions have been met and this study received unconditional approval on August 1, 2017.

Peter Rappo, MD was approved to conduct this study at the following locations:

Pediatric Associates, Inc.
370 Oak Street
Brockton, MA 02301

Pediatrics Associates, Inc.
291 East Center Street
West Bridgewater, MA 02379

Pediatrics Associates, Inc.
692 Main Street
Hanson, MA 02341

You must use the enclosed approved consent documentation stamped with "Aspire IRB Approved" located at the bottom of each page.

- **Informed Consent Document dated July 21, 2017**
- **Informed Consent Document (7-12) dated July 21, 2017**
- **Informed Consent Document (13-17) dated July 21, 2017**
- **Informed Consent Document (Parental) dated July 21, 2017**

Additional Materials:

- **Study Flyer - Approved July 21, 2017**
- **Capillary Data Collection Sheet - Acknowledged July 21, 2017**

The IRB has determined that your study is **Minimal** risk. This Board acknowledges that this study involves the proposed use of medical device that meets the criteria for an **Exempted Investigation** under 21 CFR 812.2(c). It has been assigned an approval period of **Annual** review. Your approval period ends **July 20, 2018**; as a reminder, you will receive a Research Status Report Form approximately sixty days prior to this date.

The Principal Investigator is responsible for providing the IRB with the necessary materials for re-approval by the due date provided on the form. **This form must be received by the due date to allow ample time for adequate review prior to the study's expiration date.** Missed submissions are the responsibility of the Principal Investigator regardless of whether or not the IRB notifies you.

The continuation of research after expiration of IRB approval is a violation of the regulations governing research.

Please be aware that while your study has now received IRB approval, FDA approval to proceed is still required (if applicable). It is your responsibility to ensure that you have a valid FDA approval/clearance, before you move forward with study procedures or subject recruitment. It is your responsibility to notify Aspire, if the FDA or any other regulatory agency delays or puts a hold on your research.

It is required that *Aspire IRB* be notified of:

- All amendments or changes to the protocol
- Changes to the protocol that are implemented without prior IRB approval to eliminate an apparent immediate hazard to subjects (must be reported within 24 hours of implementation)
- Unanticipated problems involving risks to subjects or others (within 10 calendar days of discovery) this includes protocol deviations that fit the criteria for an unanticipated problem.
- All material used to recruit study subjects (prior IRB approval is required before use)
- Any other changes in the research activity

The Principal Investigator may not make any changes in the research, without prior approval of *Aspire IRB,* except when necessary to eliminate immediate risk to study subjects. In addition, it is the responsibility of the Principal Investigator to uphold the following three ethical principles outlined in the Belmont Report during the conduct of this study:

- Respect for persons: individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
- Beneficence: maximize possible benefits and minimize possible harms.
- Justice: benefits and burdens of research should be distributed equally.

Aspire IRB is duly constituted and has written procedures in compliance with requirements defined in 21 CFR Parts 50 and 56, 312, 812, 45 CFR 46 and ICH Guidelines relating to Good Clinical Practice. Aspire IRB's mission is to ensure that research is conducted ethically according to the principles of the Belmont Report and in compliance with federal regulations, international regulations, ICH Guidelines for Good Clinical Practice, applicable state and local laws, Aspire IRB Standard Operating Procedures, and that the rights and welfare of human subjects are protected.

Sincerely,

Aspire IRB
AFD

Title: Research Involving Capillary Blood Draw for the Quantitation of Lead in Whole Human Blood

Sponsor: Magellan Diagnostics

Protocol Number: 276

Principal Investigator: Dr. Peter Rappo
Pediatric Associates
370 Oak Street, Suite A
Brockton, MA 02301

Telephone Number: 508-584-1210
24-Hour Telephone Number: 508-584-6934

Introduction: Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of this study.

This study is being conducted for Magellan Diagnostics. The study doctor is being paid by Magellan Diagnostics to conduct this study.

Aspire Independent Review Board (IRB) has approved the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your child's participation in the study. You must think about the information in this Consent Document for yourself. You must then decide if you want your child to be in the study.

Description: This study is designed to test an instrumented assay to be used to measure lead in human whole blood. This system is comprised of an analyzer, sensor test strips (single use, disposable), reagent vials containing a measured amount of treatment reagent, volumetric capillary tubes, controls and a calibration button.

This study is to supplement our internal data that demonstrates the continued performance of capillary blood samples on Magellan's lead testing systems: LeadCare II, LeadCare Ultra (which have been cleared previously by FDA), and PediaStat, which is an upgraded LeadCare II instrument in development.

Procedures: You will be asked to provide a sample of blood approximately the amount of a teaspoon. The blood will be taken by making a small puncture with a needle in your finger (called a fingerstick). This could potentially be done at the same time you are having blood drawn for a standard clinic visit. Other patients or individuals may choose to participate during visits when they are not due for routine blood work.

Your participation should only require the amount of time for you to carefully read and discuss this informed consent document and a few minutes for the study team to take your blood sample. Your participation will be done after the blood draw is collected.

Risks and Benefits: The risks associated with this study are: slight discomfort or pain, bruising from the blood draw, bleeding at the site where the needle enters the skin and a slight risk of infection at the site of needle entry. You will not benefit from this study as the lead test is not a new treatment study. However, if you would like to know your blood lead result, obtained by the standard laboratory method, that can be provided and may benefit you if you have not had a recent blood lead test.

Alternatives to Participation: This study is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the study.

New Findings: Regarding your participation in this study; if your laboratory values are found to be outside of the expected range, the results will be reviewed by the study doctor and he/she may have you return to the clinic for repeat or additional testing.

Compensation for Time and Travel: For your time and inconvenience related to your participation in this study, you will be paid for the study visit you complete according to the following schedule:

- $50.00 for routine study visit completion.
- $50.00 in the case that an additional visit is required to repeat the Lead testing.

Costs for Participating: There will be no charge to you or your insurance company for your participation in this study.

Compensation for Injury: The risk of injury with this test is negligible to non-existent. Should there be an injury, Magellan Diagnostics will pay the reasonable costs for necessary medical treatment that is not covered by your medical insurance provided you have followed the directions of the study doctor.

This commitment for free medical treatment does not include treatment for any other complications or illness that you may experience during this study, which does not result from your participation in the study.

Emergency Contact/IRB Contact: If you experience any medical problems or suffer a research related injury, or if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on page 1 of this consent document.

If you have any questions about your rights as a research participant and or concerns or complaints regarding this study, please call Aspire's Subject Protection Specialist at 1-877-366-5414 (toll free).

Voluntary Participation/Withdrawal: Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason at any time without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. There will be no medical consequences if you choose to withdraw from the study. The study doctor or sponsor can stop your participation at any time without your consent.

Confidentiality: Your personal information will be kept confidential to the extent permitted by law. It will only be shared with the sponsor in a de-identified manner. By signing this document, you give permission for the study staff to access your medical records, including after withdrawal, for data verification purposes.

Organizations that may inspect and/or copy your research results for quality assurance and data analysis include groups such as:

- The study staff and other researchers involved in the study
- Sponsor of this study or those who work for or represent the Sponsor
- The U.S. Food and Drug Administration (FDA)
- Aspire Independent Review Board (IRB).

The collective results from the study, including laboratory tests, may be published for scientific purposes, but your identity will be kept confidential.

SIGNATURE AND CONSENT TO BE IN THE STUDY

Your signature below means that you have read the above information about this study and have had a chance to ask questions. Your questions have been answered to your satisfaction and you voluntarily agree to be in this study. You have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this agreement. By signing this consent form, you are not giving up any of your legal rights**.**

_____

Printed Name of Participant

_____ _____/_____

Signature of Participant Date

I confirm that a copy of this consent form has been given to this person to read and that this person has been told about the study. The contents of the consent form describing the study has been discussed with this person and I have made every effort to answer all questions to his or her satisfaction. I have watched this person sign the consent form.

_____

Printed Name of Person Obtaining Consent

_____ _____/_____

Signature of Person Obtaining Consent Date

Title: Research Involving Capillary Blood Draw for the Quantitation of Lead in Whole Human Blood

Sponsor: Magellan Diagnostics

Protocol Number: 276

Principal Investigator: Dr. Peter Rappo
Pediatric Associates
370 Oak Street, Suite A
Brockton, MA 02301

Telephone Number: 508-584-1210
24-Hour Telephone Number: 508-584-6934

Introduction: Before agreeing to allow your child to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to your child and your right to withdraw your child from the study at any time. No guarantees or assurances can be made as to the results of this study.

This study is being conducted for Magellan Diagnostics. Your child's study doctor is being paid by Magellan Diagnostics to conduct this study.

Aspire Independent Review Board (IRB) has approved the information in this consent document and has given approval for the study doctor to do the study. An IRB is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your child's participation in the study. You must think about the information in this Consent Document for yourself. You must then decide if you want your child to be in the study.

Description: This study is designed to test an instrumented assay to be used to measure lead in human whole blood. This system is comprised of an analyzer, sensor test strips (single use, disposable), reagent vials containing a measured amount of treatment reagent, volumetric capillary tubes, controls and a calibration button.

This study is to supplement our internal data that demonstrates the continued performance of capillary blood samples on Magellan's lead testing systems: LeadCare II, LeadCare Ultra (which have been cleared previously by FDA), and PediaStat, which is an upgraded LeadCare II instrument in development.

Procedures: Your child will be asked to provide a sample of blood approximately the amount of a teaspoon. The blood will be taken by making a small puncture with a needle in his/her finger. This could potentially be done at the same time your child is having blood drawn for your standard clinic visit. Other patients or individuals may choose to participate during visits when they are not due for routine blood work.

Your participation should only require the amount of time for you to carefully read and discuss this informed consent document and a few minutes for the study team to take your blood sample. Your participation will be done after the blood draw is collected.

Risks and Benefits: The risks associated with this study are: slight discomfort or pain, bruising from the blood draw, bleeding at the site where the needle enters the skin and a slight risk of infection at the site of needle entry. Your child will not benefit from this study as the lead test is not a new treatment study. However, if you would like to know your child's result, obtained by the standard laboratory method, that can be provided and may benefit your child if they have not had a recent blood lead test.

Alternatives to Participation: This study is not designed to diagnose, treat or prevent any disease. Your alternative is to not have your child take part in the study.

New Findings: Regarding your child's participation in this study; if your child's laboratory values are found to be outside of the expected range, the results will be reviewed by your doctor and he/she may have you return to the clinic for repeat or additional testing.

Compensation for Time and Travel: For your time and inconvenience related to your child's participation in this study, you will be paid for the study visit your child completes according to the following schedule:

- $50.00 for routine study visit completion.
- $50.00 in the case that an additional visit is required to repeat the Lead testing.

Costs for Participating: There will be no charge to you or your insurance company for your child's participation in this study.

Compensation for Injury: The risk of injury with this test is negligible to non-existent. Should there be an injury, Magellan Diagnostics will pay the reasonable costs for necessary medical treatment that is not covered by your medical insurance provided you have followed the directions of the study doctor. This commitment for free medical treatment does not include treatment for any other complications or illness that you may experience during this study, which does not result from your participation in the study.

Emergency Contact/IRB Contact: If your child experiences any medical problems or suffers a research related injury, or if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on page 1 of this consent document.

If you have any questions about your child's rights as a research participant and or concerns or complaints regarding this study, please call Aspire's Subject Protection Specialist at 1-877-366-5414 (toll free).

Voluntary Participation/Withdrawal: Your decision to allow your child to participate in this study is voluntary. You may choose to not allow your child to participate or you may withdraw your child from the study for any reason at any time without penalty or loss of benefits to which your child is otherwise entitled and without any effect on your child's future medical care. There will be no medical consequences if you choose to withdraw your child from the study. The study doctor or sponsor can stop your child's participation at any time without your consent.

Confidentiality: Your child's personal information will be kept confidential to the extent permitted by law. It will only be shared with the sponsor in a de-identified manner. By signing this document, you give permission for the study staff to access your child's medical records, including after withdrawal, for data verification purposes.

Organizations that may inspect and/or copy your child's research results for quality assurance and data analysis include groups such as:

- The study staff and other researchers involved in the study
- Sponsor of this study or those who work for or represent the Sponsor
- The U.S. Food and Drug Administration (FDA)
- Aspire Independent Review Board (IRB).

The collective results from the study, including laboratory tests, may be published for scientific purposes, but your child's identity will be kept confidential.

SIGNATURE AND CONSENT TO BE IN THE STUDY

Your signature below means that you have read the above information about this study and have had a chance to ask questions. Your questions have been answered to your satisfaction and you voluntarily agree to allow your child to be in this study. You have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this agreement. By signing this consent form, you are not giving up any of your legal rights.

_____

Printed Name of Parent

_____ _____/_____

Signature of Parent Date

_____

Printed Name of Child

I confirm that a copy of this consent form has been given to this person to read and that this person has been told about the study. The contents of the consent form describing the study has been discussed with this person and I have made every effort to answer all questions to his or her satisfaction. I have watched this person sign the consent form.

_____

Printed Name of Person Obtaining Consent

_____ _____/_____

Signature of Person Obtaining Consent Date

ASSENT DOCUMENT
AGES 13 - 17

Title: Research Involving Capillary Blood Draw for the Quantitation of Lead in Whole Human Blood

Sponsor: Magellan Diagnostics

Protocol Number: 276

Principal Investigator: Dr. Peter Rappo
Pediatric Associates
370 Oak Street, Suite A
Brockton, MA 02301

Telephone Number: 508-584-1210
24-Hour Telephone Number: 508-584-6934

You are being asked to be in a research study. Research studies include only people who choose to be in them. You are being asked to be in this study because you are/ in a specific age group from 13-17 years old. Please take your time to make your decision. Talk to your family about it. Be sure to ask any questions that you may have before you decide.

STUDY INVESTIGATOR AND SPONSOR

Dr. Rappo at Pediatrics Associates is performing a research study for Magellan Diagnostics to assist in collecting samples from specific age groups and laboratory reference ranges to complete their clinical studies.

WHY IS THIS STUDY BEING DONE?

This study is being performed to help us build an easy screening method for pediatricians to use in their office when they need to test for lead using a small amount of blood. Currently, we have are two separate tests. They are called: LeadCare II and LeadCare Ultra. We are developing an updated version of the LeadCare II tests; we call it PediaStat. The FDA (Food and Drug Administration) needs more information from specific age groups and reference ranges so they are confident that they have enough data for them to decide whether they should approve this type of blood test.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

We hope to have about 190 people participate in this study.

HOW LONG WILL YOU BE IN THE STUDY?

This most likely will be a one-time donation of your blood. It should only take a few minutes during your doctor's visit. You may be called back if the study needs to be repeated.

You can stop being in the study at any time. Because these tests are duplicates of existing "well" visit tests normally done by the doctor, there will be no effect on your health by agreeing to participate. The doctor will not use this test to make any decisions about your health.

WHAT IS INVOLVED IN THE STUDY?

This is what will happen at your study visit:

- You will arrive at your study location.
- The nurse or study coordinator will have you read and sign some paperwork. They will talk to you about what you are being asked to do and answer all of your questions. Please make sure to ask if you have any questions.
- Dr. Rappo, or someone on the physicians' staff, will collect a blood sample from you. This will be done with a capillary stick (also called a fingerstick).

WHAT ARE THE RISKS OF THE STUDY?

The risks and side effects are similar to any blood draw. They include these things:

- A little bit of pain or pinch at the place where the needle sticks you
- Slight bruising
- Possible slight bleeding afterwards

Any other side effects related to the site where blood is drawn should be discussed with Dr. Rappo or one of the nurses.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Because this test is not being used to help the doctor make decisions about your health, you will not get any direct benefit from being in this research study. This information will help Magellan develop tests that may help doctors help their patients in the future.

WHAT OTHER OPTIONS ARE THERE?

Because this research isn't being used to help your health, your only alternative is to choose not to be in this research study. Saying no to being in this study will not stop you from being able to participate in any other future research opportunities offered by Pediatrics Associates or Magellan Diagnostics.

CAN YOU BE REMOVED FROM THE STUDY WITHOUT YOUR CONSENT?

Dr. Rappo can take you out of the study if he thinks it is not good for you, if you can't follow the rules of the study or the study itself closes sooner than expected.

WHAT ABOUT CONFIDENTIALITY?

We will do everything we can to keep your records private and confidential. Magellan Diagnostics will not have access to your patient information. But we do have to let some people look at your records. The people can see your records are:

- Aspire Independent Review Board (a group of people that looks out for the protection of human subjects in research)
- Other regulatory agencies responsible for overseeing research, such as the federal Office for Human Research Protections or the US Food and Drug Administration

We will keep your records confidential unless we are required by law to share any information.

Dr. Rappo may decide to publish a paper on the results of this study. If that happens, no one will know you were in the study.

WILL YOU GET PAID TO BE IN THIS STUDY?

Participation in this study is completely voluntary. You will be paid with a $50 Visa gift card for being in this study.

WHAT IF YOU ARE INJURED IN THE STUDY?

If you are injured or become ill as a direct result of this research study, your study doctor will take care of you or s/he will make sure you get the care you need.
As this is simply a blood draw, the risk of this is extremely low.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have any questions, concerns, or complaints about the study or an injury that you think was caused by being in this research study, you or your parent(s) should please call Dr. Rappo at 508-584-1210.

If you have any questions about your rights as a research participant and or concerns or complaints regarding this study, you or your parent(s) should please call Aspire's Subject Protection Specialist at 1-877-366-5414 (toll free).

WHAT ARE YOUR RIGHTS AS A RESEARCH SUBJECT?

You don't have to be in this study if you don't want to or you can stop being in the study any time you want to. Your study doctor and the study won't be angry with you and there won't be any penalty or loss of benefits that you have now.

Aspire IRB has approved this research study, but only you can decide if being in this study is the right choice for you.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

AGREEMENT TO BE IN THE STUDY

Your signature below means that you have read the information about the study and have had a chance to ask questions to help you understand what you will do in this study. Your signature also means that you have been told that you can change your mind later if you want to. You will be given a signed and dated copy of this assent form. By signing this assent form, you are not giving up any of your legal rights.

Your parent or legal guardian will be given another document called an informed consent that they are also required to sign if you choose to participate. You will be given a copy of this document as well.

Be sure to ask Dr. Rappo to tell you more about anything that you don't understand.

☐ Yes, you will be in this research study. ☐ No, you don't want to do this.

_____ _____
Name of Participant Age

_____ _____
Signature of Participant (12 - 17 years of age) Date

_____
Printed Name of Person Who Explained This Form

_____ _____
Signature of Person Who Explained This Form Date

ASSENT DOCUMENT
AGES 7 - 12

Research Involving Fingerstick Blood Collection for the Quantitation of Lead in Whole Human Blood

Sponsor:	Magellan Diagnostics
Protocol Number:	276
Principal Investigator:	Dr. Peter Rappo Pediatric Associates 370 Oak Street, Suite A Brockton, MA 02301
Telephone Number:	508-584-1210
24-Hour Telephone Number:	508-584-6934

Dr. Rappo is doing a research study to find out how well a new test system works that measures the levels of something in your blood called lead. Dr. Rappo wants to know if you want to be in this research study because you are of the right age.

If you say yes, this is what will happen to you:

Dr. Rappo, or someone on staff, will collect a blood sample from you today. This is done with a prick of your finger.

When the blood is taken from your finger, you may experience or feel:

- A little bit of pain
- Slight bruising
- A little bleeding afterwards

If you feel any of these things, or something else, be sure to tell your mom or dad.

If you are afraid or do not like blood collection, you don't have to be in this research study if you don't want to. Nobody will be mad at you if you say no. Even if you say yes now and change your mind after you start doing this study, you can stop and no one will be mad.

Be sure to ask Dr. Rappo to tell you more about anything that you don't understand.

❑ Yes, you will be in this research study. ❑ No, you don't want to do this.

_____ _____
Write your name on this line Date

_____
Printed Name of Person Who Explained This Form

_____ _____
Signature of Person Who Explained This Form Date