

Appendix Q: Report to Participant – Abnormal Values (Mailed Follow-up)

SAMPLE LETTER – ABNORMAL RESULTS
(Version 0.9)



A health study for oil spill clean-up workers and volunteers

«TITLE» «PARTICIPANT FIRST» «PARTICIPANT LAST»
«STREET ADDRESS 1»
«STREET ADDRESS 2»
«CITY», «STATE» «ZIP CODE»

«DATE»

Dear «TITLE» «PARTICIPANT LAST»:

On behalf of the entire GuLF Study team, I want to thank you for your dedication in completing your telephone interview and home visit. We know that it took a considerable amount of your time to do all of this and it is greatly appreciated.

As part of your participation in the GuLF Study, you met with «HVA name» on «date» and completed a questionnaire and a number of clinical evaluations. Our records indicate that at least one of your evaluation findings was abnormal. The enclosed report summarizes the evaluation findings and provides advice for following up on any abnormal results. The summary report also includes the results of your lung function test «[IF IN BIOMEDICAL SUBCOHORT] and complete blood count», which were not provided to you during your visit. We encourage you to follow all the advice in the report, if you have not done so already.

If you have any questions about your results or need assistance with a referral for health care, please call the study center toll-free at 1-855-NIH-GULF (1-855-644-4853). IF REQUESTED THAT RESULTS BE SENT TO HEALTH CARE PROVIDER: <<A copy of the enclosed summary report has also been sent to your health care provider, «Health Care Provider Name».>>

As you know, the GuLF Study is a long-term study and we plan to keep in touch with you for at least the next ten years.

- We will send you newsletters each year with the latest updates on the study. Keeping you posted on GuLF Study events and findings is important to us.
- Every two years, we will ask you to complete a short telephone interview about your health and environment.
- In the years between calls, we will contact you by mail to request updated contact information.

- [ADDITIONAL TEXT FOR BIOMEDICAL SUB-COHORT:] << You may also be invited to participate in additional studies with our research partners.>>

Please keep in touch and visit our website at www.nihgulfstudy.org for news about the GuLF Study. If you have any questions, please call us toll-free at 1-855-NIH-GULF(1-855-644-4853). Our hours are Monday through Saturday (9am – 9pm) and Sunday (12pm – 6pm) Eastern Time. [TIME ADJUSTED TO LOCAL TIME ZONE].

Sincerely,

Dale Sander
Principal Investigator, GuLF Study
National Institute of Environmental Health Sciences
National Institutes of Health

SAMPLE REPORT OF FINDINGS

Date of Study Visit: «Date»
Name: «Participant Name»
Age: «Age»
Gender: «Gender»

Body Measurements

Height: «feet, inches»

Weight: «pounds»

Body Mass Index: «BMI»

Advice: *[CUSTOMIZED TO THE RESULTS OF THE PARTICIPANT]*

If BMI is > 30:

Your BMI indicates that your weight is in the **obese** range for adults of your height. People who are obese are at higher risk for chronic conditions such as high blood pressure, diabetes, and high cholesterol. You should talk to your health care provider about this finding and any need for additional evaluation or consultation.

If BMI is between 25 and 29.9:

Your BMI indicates that your weight is in the overweight range for adults of your height. People who are overweight may be at higher risk for chronic conditions such as high blood pressure, diabetes, and high cholesterol. You should talk to your health care provider about this finding and any need for additional evaluation or consultation.

If BMI is between 18.5 and 24.9:

Your BMI indicates that your weight is in the normal range for adults of your height. Maintaining a healthy weight may reduce the risk of chronic diseases associated with overweight and obesity.

If BMI is <18.5

Your BMI indicates that your weight is in the underweight category for adults of your height. Talk with your health care provider to discuss this finding and any need for additional evaluation or consultation.

If height and/or weight were not measured, omit the standard text and the results table. Display the following message:

You BMI could not be calculated because we did not have complete height and weight measurements from your home visit.

| |
|-----------------------|
| Blood Pressure |
|-----------------------|

| | Measurement 1 | Measurement 2 | Measurement 3 | Average |
|--------------|---------------|---------------|---------------|---------|
| Systolic BP | «SBP» | «SBP» | «SBP» | «SBP» |
| Diastolic BP | «DBP» | «DBP» | «DBP» | «DBP» |

Advice:

<<Display the header and the row appropriate for the results>>

| Your blood pressure readings are (mm Hg) | This is considered | You are advised to |
|--|---------------------------|---|
| Systolic BP \geq 180 OR Diastolic BP \geq 110 | Emergency | Call 911 or go to the emergency department immediately. Emergency Care Needed. |
| Systolic BP 160 to 179 OR Diastolic BP 100 to 109 | Very High | See a health care provider within the next month to have your blood pressure rechecked and managed. |
| Systolic BP 140 to 159 OR Diastolic BP 90 to 99 | Mildly to Moderately High | See a health care provider within the next two months to have your blood pressure rechecked and managed. |
| Systolic BP 120 to 139 OR Diastolic BP 80 to 89 | Slightly High | Find out from a health care provider if any additional evaluations or lifestyle changes are indicated. |
| Systolic BP <120 AND Diastolic BP <80 | Normal | Your Blood Pressure is within normal limits. Talk to a health care provider about healthy lifestyle choices that you can take to prevent high blood pressure. |

If blood pressure was not measure, omit the standard text and the results table. Display the following message:

Blood pressure measurements were not taken during your visit. Therefore, we cannot provide you with meaningful results.

Urine glucose (sugar)

Results:

| | |
|-------------------------------------|------------------|
| Recent symptoms of diabetes: | «Yes/No» |
| Previously diagnosed with diabetes: | «Yes/No» |
| Urine Glucose Result: | «0 to \geq 2%» |

Advice:

<<Display the header and the row appropriate for the results>>

| This is considered | You are advised to |
|----------------------|--|
| Urgent | See a health care provider <u>within the next week</u> to have your glucose levels checked again |
| Of potential concern | See a health care provider <u>within the next month</u> to have your glucose levels checked again or sooner if symptoms should appear or worsen |
| Normal | No follow-up action is required |

Lung Function Test

| | Your Best Values | Predicted Values | Lower Limit of Normal |
|----------------------------|------------------|------------------|-----------------------|
| FVC (L) | «value» | «value» | «value» |
| FEV ₁ (L) | «value» | «value» | «value» |
| FEV ₁ / FVC (%) | «value» | «value» | «value» |

The purpose of the pulmonary function test, also known as spirometry or lung function test, is to determine how your lung function compares to normal lung function for someone of your age, gender, race, and height. The table above provides your results for three measurements.

- The forced vital capacity (FVC) is the maximal or total amount of air you can forcefully breathe out after taking a deep breath.
- The 1-second forced expiratory volume (FEV₁) is the amount of air that you can breathe out in the first second of exhaling.
- The FEV₁ / FVC (%) is the calculation of the ratio of FEV₁ to FVC.

The table also compares your results to predicted values for a healthy, non-smoking person of the same age, height, sex, and race.

Your results have been reviewed by an expert in lung function testing. Please note that any abnormal test result is not a diagnosis of disease; that determination can only be made a health care provider following a complete medical examination.

If FVC, FEV₁, and FEV₁ / FVC are all above the lower limit of normal

Interpretation: Your lung function test results were within normal limits.

If either the FVC, FEV₁, or FEV₁ / FVC are below the lower limit of normal and FEV₁ % predicted is <50%:

Interpretation: Your lung function test results were interpreted as being abnormally low. You are advised to see a health care provider **as soon as possible**, if you have not done so already.

If either the FVC, FEV₁, or FEV₁ / FVC are below the lower limit of normal and FEV₁ % predicted is ≥ 50%:

Interpretation: Your lung function test results were interpreted as being abnormally low. You are advised to see a health care **within a month**.

If results could not be interpreted due to low quality:

Interpretation: Your lung function test results were not interpretable.

If lung function testing was expected, but not done, omit the standard text and the results table. Display the following message:

A lung function test was not completed during your home visit.

If the test was not performed by the participant, omit the entire section.

| |
|-----------------------------|
| Complete Blood Count |
|-----------------------------|

| | Result | Units | Flag | Normal Range |
|------------------------------|---------|------------------------|---------|-------------------|
| Total White Blood Cell Count | «value» | (x10 ³ /µL) | «value» | «value» - «value» |
| Hemoglobin | «value» | (g/dl) | «value» | «value» - «value» |
| Hematocrit | «value» | (%) | «value» | «value» - «value» |
| Platelet Count | «value» | (x10 ³ /µL) | «value» | «value» - «value» |

Advice:

<<Display advice based on lab results>>

| ANALYTE | RESULTS | ADVICE |
|-------------------------------------|--|---|
| Total White Blood Cell Count | ALERT LEVEL All: ≤ 1.1 x 10 ³ | Your results should be reviewed by a health care provider as soon as possible. You are advised to see your health care provider within one week of receiving your results. |
| | Results between alert level and normal reference range | Your results are slightly out of range. You are advised to see your health care provider within two months of receiving your results. |
| | Within lab normal reference range | Your results are normal. You are encouraged to share your results with your health care |

| | | |
|-------------------|---|---|
| | | provider at your next appointment. |
| Hemoglobin | ALERT LEVEL Males: <12; >20 Females: <10; >17 | Your results should be reviewed by a health care provider as soon as possible. You are advised to see your health care provider within one week of receiving your results. |
| | Results between alert level and normal reference range | Your results are slightly out of range. You are advised to see your health care provider within two months of receiving your results. |
| | Within lab normal reference range | Your results are normal. You are encouraged to share your results with your health care provider at your next appointment. |
| Hematocrit | ALERT LEVEL Males <35; >53 Females <30; >50 | Your results should be reviewed by a health care provider as soon as possible. You are advised to see your health care provider within one week of receiving your results. |
| | Results between alert level and normal reference range | Your results are slightly out of range. You are advised to see your health care provider within two months of receiving your results. |
| | Within lab normal reference range | Your results are normal. You are encouraged to share your results with your health care provider at your next appointment. |
| Platelets | ALERT LEVEL <50 x 10 ³ ; >500 x 10 ³ | Your results should be reviewed by a health care provider as soon as possible. You are advised to see your health care provider within one week of receiving your results. |

| | | |
|--|--|--|
| | Results between alert level and normal reference range | Your results are slightly out of range. You are advised to see your health care provider within two months of receiving your results. |
| | Within lab normal reference range | Your results are normal. You are encouraged to share your results with your health care provider at your next appointment. |

If blood collection was expected, but not done, omit the standard text and the results table. Display the following message:

A blood sample for the complete blood count was not collected during your home visit.

If the participant is not in the biomedical sub-cohort, omit entire section.