

Study GDS01C

SPMSD

Vaccination Report Card (9 – 15 Years of Age)

Only the Subject or the PARENT or GUARDIAN of the subject should complete this vaccination report card. Corrections to the vaccination report card by the subject or parent or guardian should be dated and initialled by the subject or parent or guardian.

The STUDY NURSE / INVESTIGATOR will enter the dates where needed.

Subject allocation number:

Given at Visit:

Visit 1

Visit 2

Visit 3

Complete this card for **15 days after vaccination** (until _____)
day/month/year
and return the card to the study site when it is complete.

Study Personnel / Investigator Telephone Number: _____

Subject, Parent or Guardian's Comments:

Study Site Personnel / Investigator Comments:

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TEMPERATURE MEASUREMENT

It is important that you take your daughter's temperature every day starting with the day of vaccination through Day 5.

Take your daughter's temperature orally and record this temperature in the appropriate box below.

Take your daughter's temperature in the evening whenever possible. If you need to take your daughter's temperature more than once during a day, record the highest temperature taken that day.

TAKE ORAL TEMPERATURE EACH DAY

DAY	DATE (day/month/year)	ORAL TEMPERATURE
1.		
2.		
3.		
4.		
5.		

I have reviewed this information.

Staff's initials:

Date:

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INSTRUCTIONS FOR INJECTION SITE REACTIONS:

On the following page entitled "Injection Site Reactions", please measure any **swelling** or **redness** AT THE INJECTION SITE.

Estimate the **size** of the reaction at its largest from edge to edge. Use the ruler marks along the bottom of the page.

Mark the box that best describes the size of the reaction:

- 1 if the greatest width is anywhere in the area marked 1 (**Example A**)
 - 2 if the greatest width is anywhere in the area marked 2
 - 3 if the greatest width is anywhere in the area marked 3 (**Example B**)
 - Over 3** if the greatest width is in any area marked with a number over 3.
- Write* in the number. (**Example C**)
If the reaction is wider than the area marked 7, write in 8.

On the following page entitled "Injection Site Reactions", please estimate the severity of any **pain** or **tenderness** or **other reactions** AT THE INJECTION SITE.

Mark the box that best describes the severity of the reaction using the following definitions:

- mild** is awareness of symptom, but easily tolerated
- moderate** is definitely acting like something is wrong
- severe** is extremely distressed or unable to do usual activities

Complete one column each day, starting with Day 1 (the day of vaccination – 4 hours after injection). If the reaction continues past Day 5, please write in the last date it was present.

If an injection site reaction begins after Day 5, please estimate the severity of the reaction in the box at the bottom of the pages entitled "Injection Site Reactions".

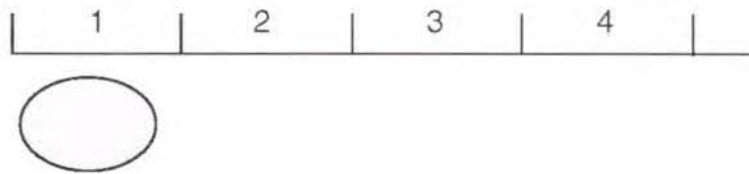
1	2	3	4	5	6	7	8 →
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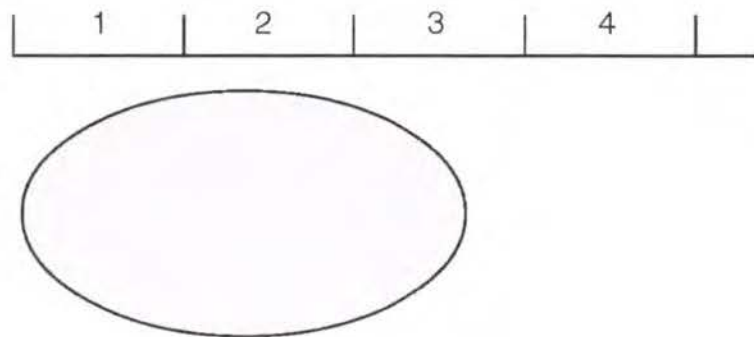
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**EXAMPLES FOR MEASURING
THE SIZE OF REACTIONS:**

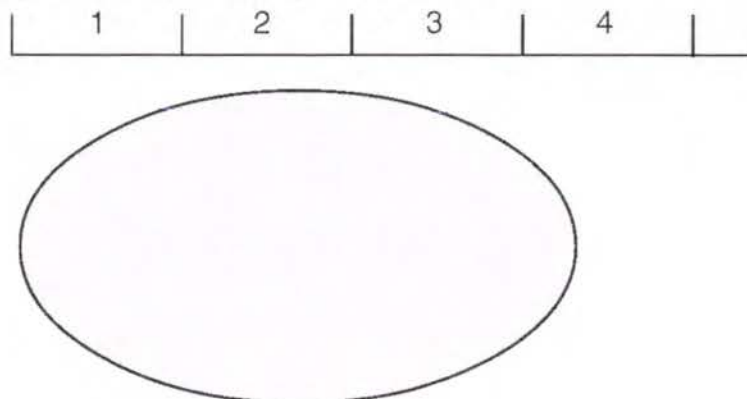
Example A: This reaction falls in the area marked 1 at its largest, so you would check the box marked "1".



Example B: This reaction falls in the area marked 3 at its largest, so you would check the box marked "3".



Example C: This reaction falls in the area marked 4 at its largest, so you would check the box marked "Over 3" and write in a 4.



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INJECTION SITE REACTIONS

Complete one copy of this page per injection site. Indicate the injection site by checking one box below.
 Injection Site: Right Arm Left Arm
 Other _____

	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	LAST DATE REACTION PRESENT
	Vaccination Day					
	_____	_____	_____	_____	_____	
	day/month/year	day/month/year	day/month/year	day/month/year	day/month/year	
SWELLING	None	None	None	None	None	_____
	1	1	1	1	1	
	2	2	2	2	2	
	3	3	3	3	3	
	over 3: _____	over 3: _____	over 3: _____	over 3: _____	over 3: _____	day/month/year
REDNESS	None	None	None	None	None	_____
	1	1	1	1	1	
	2	2	2	2	2	
	3	3	3	3	3	
	over 3: _____	over 3: _____	over 3: _____	over 3: _____	over 3: _____	day/month/year

PAIN or TENDERNESS	None	None	None	None	None	_____
	Mild	Mild	Mild	Mild	Mild	
	Moderate	Moderate	Moderate	Moderate	Moderate	day/month/year
	Severe	Severe	Severe	Severe	Severe	
OTHER INJECTION SITE REACTION <i>(specify):</i> _____	None	None	None	None	None	_____
	Mild	Mild	Mild	Mild	Mild	
	Moderate	Moderate	Moderate	Moderate	Moderate	day/month/year
	Severe	Severe	Severe	Severe	Severe	
OTHER INJECTION SITE REACTION <i>(specify):</i> _____	None	None	None	None	None	_____
	Mild	Mild	Mild	Mild	Mild	
	Moderate	Moderate	Moderate	Moderate	Moderate	day/month/year
	Severe	Severe	Severe	Severe	Severe	

If an injection site reaction **began** 6 or more days after your daughter's vaccination, please record it below. Record the date it **started** and the **last date it was present**. Mark the box that best describes the severity of the injection site reaction.

INJECTION SITE REACTIONS BEGINNING 6 OR MORE DAYS AFTER VACCINATION	DATE (day/month/year)		SEVERITY		
	Started	Last Present			
			Mild	moderate	severe
			Mild	moderate	severe

1	2	3	4	5	6	7	8 →
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OTHER COMPLAINTS OR ILLNESSES

Record any other complaints or illnesses which developed or worsened during the 15 days after vaccination.

Record the date it **started** and the **last date it was present**.

Mark the box that best describes the severity of the complaint using the following definitions:

mild is awareness of symptom, but easily tolerated

moderate definitely acting like something is wrong

severe is extremely distressed or unable to do usual activities

Do not record injection site complaints on this page. Those complaints are recorded on the previous page in the table entitled "Injection Site Reactions".

List each complaint or illness separately.

If during the 15 days after vaccination your daughter did not have any other complaints or illnesses check the box here: **None**

OTHER COMPLAINTS OR ILLNESSES	DATE (day/month/year)		SEVERITY		
	Started	Last Present			
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe
			mild	moderate	severe

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MEDICATIONS

Please list any prescription or over the counter medications your daughter takes starting from Day 1 _____ through Day 15 _____ after your daughter's injection.
day/month/year day/month/year

LIST THE NAME OF THE MEDICATION	DATE MEDICATION STARTED <small>(day/month/year)</small>	DATE MEDICATION LAST TAKEN <small>(day/month/year)</small>	REASON FOR TAKING THE MEDICATION

NON-STUDY VACCINATIONS

Record any vaccines administered during the 15 days after your daughter received the study vaccine and report card.

LIST VACCINATION	SITE OF VACCINATION					DATE RECEIVED <small>(day/month/year)</small>
	Right Arm	Left Arm	Right Thigh	Left Thigh	Other _____	
	Right Arm	Left Arm	Right Thigh	Left Thigh	Other _____	
	Right Arm	Left Arm	Right Thigh	Left Thigh	Other _____	

I confirm that the information on this card is accurate

_____ (Parent's Initials) _____ (Date when follow-up is completed)